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CLINICAL INVESTIGATION PROGRAM FISCAL YEAR 1987(U)  
TRIPLER ARMY MEDICAL CENTER HI DEPT OF CLINICAL  
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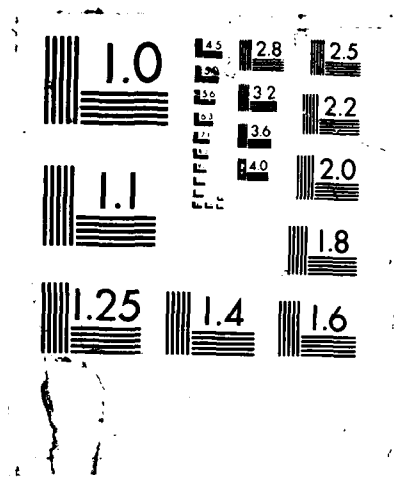
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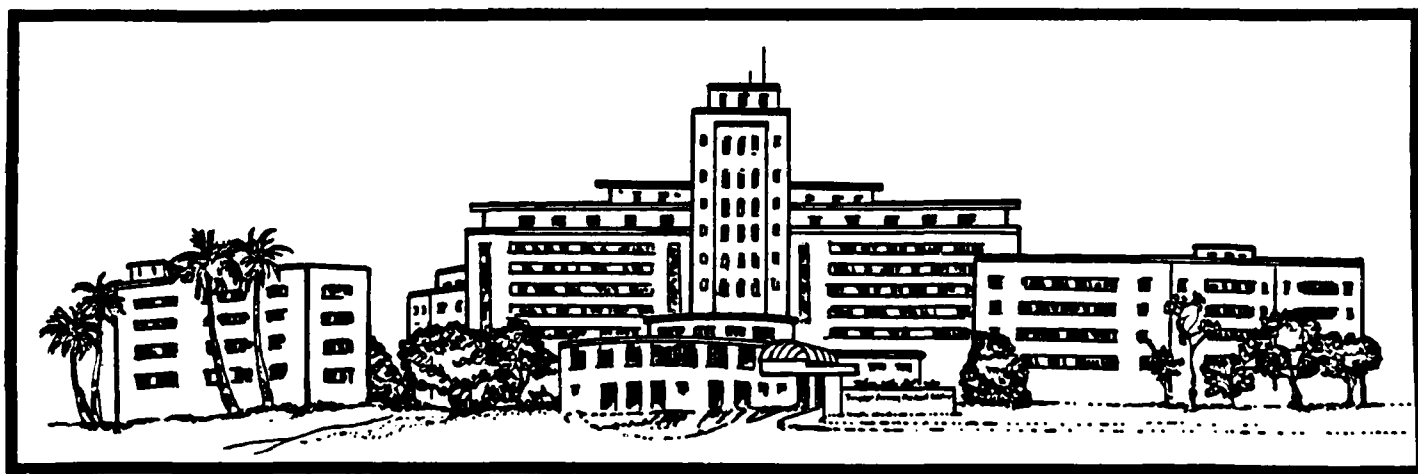


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# TRIPLER ARMY MEDICAL CENTER



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## CLINICAL INVESTIGATION PROGRAM REPORTS CONTROL SYMBOL MED-300 (R1) FISCAL YEAR 1987

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19. KEY WORDS (Continue on reverse side if necessary and identify by block number) Clinical investigation; experimental projects; research projects; in-house research; publications, presentations of research data; project status; experimental design, <i>infectious pathology, immunology, oncology</i>		
20. ABSTRACT (Continue on reverse side if necessary and identify by block number) Subject report identifies those individuals who are conducting investigative protocols at Tripler Army Medical Center. An abstract of each project giving abbreviated technical objectives, methods, and progress is presented.		

# ANNUAL PROGRESS REPORT

DEPARTMENT OF CLINICAL INVESTIGATION  
Reports Control Symbol MED-300(R-1)

FISCAL YEAR 1987  
1 October 1987

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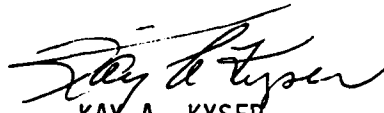
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## FOREWORD

Tripler AMC Clinical Investigation lost its chief, its immunologist and two authorizations during the year. At a time of increasing interest in research both within Tripler and by outside reviewing agencies, the department has reached a point of near incomplete inability to meet its mission. It will take years of command emphasis and commitment from throughout TAMC to bring clinical investigation to the level required by a modern referral center.

A strong point is the physiology program which receives increasing interest from residents, fellows and graduate students. Dr. Claybaugh was named to the editorial board of two more journals. CPT Freund's research is at a level of full production. It is important that the turbulence of the facility, staffing, and policy changes that must occur not interrupt the productivity of this area.

Also on the positive side is command and staff commitment at both TAMC and HSC levels for improved support of clinical investigation. That commitment is critical.



KAY A. KYSER  
Colonel, MC  
Chief, Dept of Clinical Investigation

DEPARTMENT OF CLINICAL INVESTIGATION  
TRIPLER ARMY MEDICAL CENTER

UNIT SUMMARY

A. OBJECTIVES: To sponsor clinical investigation, in compliance with applicable laws, regulations and policies, to increase the academic professional stature of the MEDCEN.

B. TECHNICAL APPROACH: 1) Renew research documentation and advise the Commander and his institutional committees on matters pertaining to clinical investigation, and 2) Provide consultative and collaborative support to approved investigations.

C. STAFFING:

<u>Name</u>	<u>Rank</u>	<u>MOS</u>	<u>Title</u>
Kyser, Kay A.	COL	61F9B	Chief
McCullen, Albert H.	MAJ	64C9B	Chief, Veterinary Service
Freund, Beau J.	CPT	68J00	Research Physiologist
Conceicao, Mary Lou	SSG	92B30	NCOIC
Leininger, Harold V.	SSG	91T30	Animal Care Specialist
Brady, Anne V.	SGT	01H2R	Biological Science Asst
Choate, James W.	SP4	92B10	Medical Laboratory Specialist
Penrose, Tammie J.	SGT	91T2R	Animal Care Specialist
Ahlman, Timothy M.	PFC	91T10	Animal Care Specialist
Lauersen, Sandra J.	SP4	91T10	Animal Care Specialist
Claybaugh, John R.	GM14	00413	Chief, Physiology Service
Ichimura Wayne M.	GS11	00802	Biomedical Engineer
Hashiro, Glenn M.	GS09	00404	Biological Laboratory Tech
Sato, Aileen K.	GS09	00644	Medical Technologist
Kullama, Linda K.	GS07	00404	Biological Laboratory Tech
Abe, Sharon M.	GS07	01087	Editorial Assistant
Leighnor, Agatha M.	GS05	00318	Secretary (Typing)
Finn, Kuuleialoha M.	GS05	00404	Biological Aide (Part-time)
Dice, Margaret S.*	GS04	00404	Biological Aide (Part-time)
Albert, Thomas G.	WG04	03566	Animal Caretaker

\*On USAMRDC grant

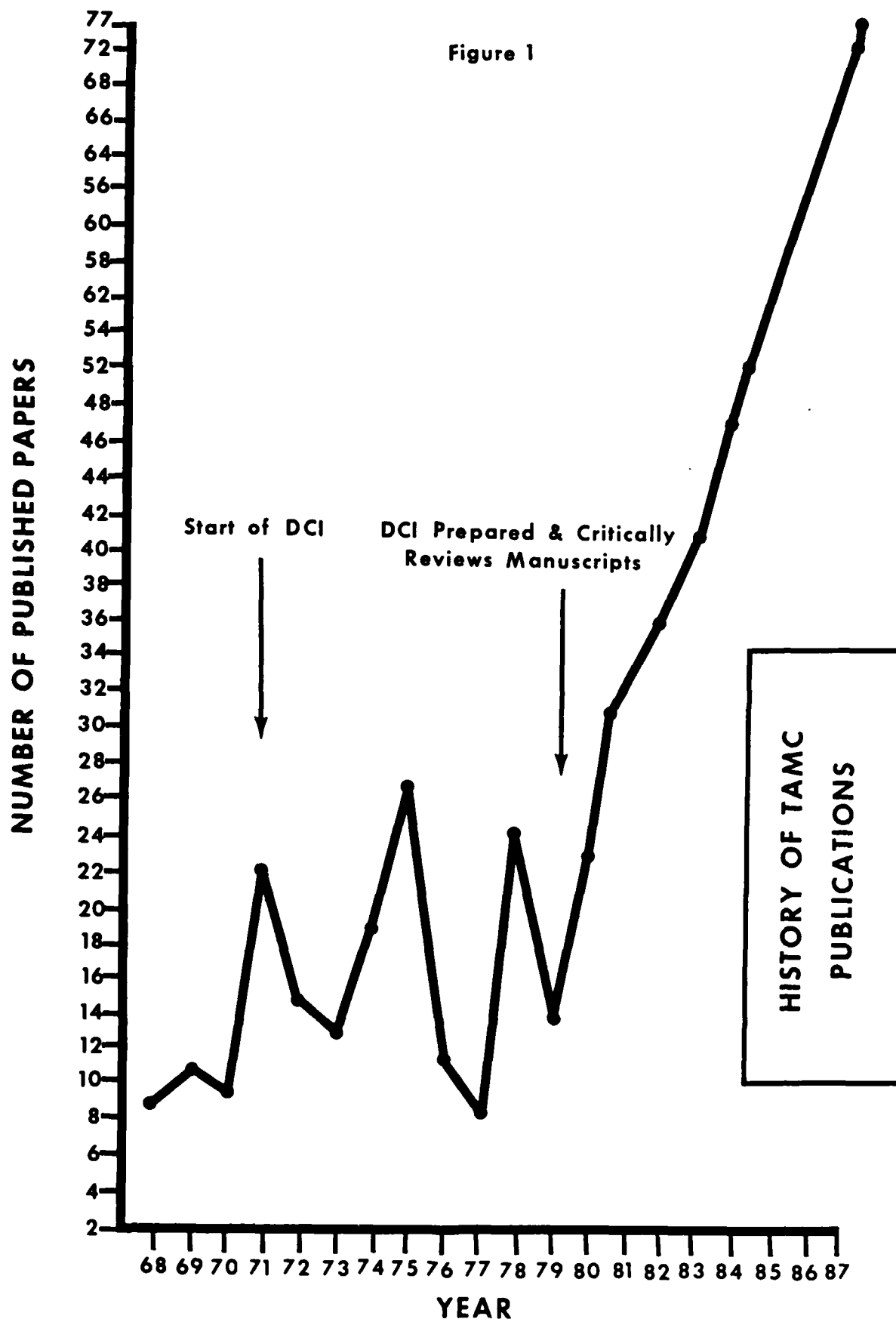


D. FUNDING:

Funding Type	1986	USMRDC Grant 1986	1987	USMRDC Grant 1987
Civilian personnel including benefits	\$257,622	\$ 49,289	\$244,501	\$ 27,043
Consumable supplies	130,368	5,326	109,842	4,090
Civilian contracts including consultants	5,966	1,224	27,433	
TDY	33,564		26,904	
Publications	3,016		3,208	
Noninvestment equipment (Minor MEDCASE)	0		1,390	
Other OMA      Trans & Taxes Rentals	750		473	
OMA Total	431,286	45,739	413,751	31,133
MEDCASE	50,615		65,890	
Military	404,008		428,712	
TOTAL	\$885,909	45,739	908,353	31,133

E. PROGRESS: No progress was made in recent years in areas of policy, staffing or space. Number of authorizations actually decreased. Facility support remained nonexistent (not even electric plugs repaired).

F. PROBLEMS: See progress.



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Kennon WG: Phase Contrast Microscopy in the Diagnosis of Hematuria. American Urological Association 63rd Annual Meeting, Kona, HI, Feb 1987

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Pliskin MJ, Dresner ML, Kennon WG, Kreder KJ, Desmond PM, Soderdahl DW: The Use of Intraurethral Cocaine Anesthesia in Male Outpatient Cystoscopy. Western Section AUA Meeting, Kona, HI, Feb 1987

Pliskin MJ: Renal Cell Carcinoma in a Cadaver Donor Kidney. American Urological Association 63rd Ann Meeting, Kona, HI, Feb 1987

Pliskin MJ: Use of Cocaine in Outpatient Cystoscopy. American Urological Association 63rd Ann Meeting, Kona, HI, 1987

Raterink MH: Fungal Sinusitis. American Academy of Otolaryngology-Head and Neck Surgery Ann Meeting, Chicago, IL, Sep 1987

Reinker KA: Osteomyelitis of the Spine in Children. 15th Ann Symposium of Children's Orthopaedics, Fitzsimmons Army Medical Center, Aurora, CO, Feb 1987

Reinker KA: Biomechanics. Dwight D Eisenhower Army Medical Center, Fort Gordon, GA and Medical College of Georgia, Augusta, GA, May 1987

Reinker KA: Osteomyelitis of the Spine in Children. 1987 Hawaii Orthopaedic Association Spring Symposium, Honolulu, HI, Jun 1987

Romash MM, Fugate DS: Passive Range of Motion of the Great Toe Ray -- Preoperative Assessment. 28th Ann Meeting of the Society of Military Orthopaedic Surgeons, Colorado Springs, CO, Nov 1986

Romash MM, Henningsen JR: Knee Braces - Comparartive Functional Testing. 28th Ann Meeting of the Society of Military Orthopaedic Surgeons, Colorado Springs, CO, Nov 1986

Romash MM: Unique Prosthetic Problems for Pacific Islands; Mobility. Innovations & Applications in Rehabilitation Seminar, the Outrigger Prince Kuhio Hotel, Honolulu, HI, Feb 1987

Romash MM: Passive Range of Motion of the Great Toe Ray - Preoperative Assessment. 17th Ann Meeting of the American Orthopaedic Foot and Ankle Society, Inc, San Francisco, CA, Jan 1987

Romash MM: Knee Braces - Comparative Functional Testing. 54th Ann Meeting of the American Academy of Orthopaedic Surgeons, San Francisco, CA, Jan 1987

Saracino D, Barcia PJ: D-Lactic Acidosis in Acute Abdominal Conditions. Wm Beaumont GI Symposium, San Francisco, CA, Oct 1986

Schuchmann GD, Barcia PJ: Phosphate Absorption from Enema in Adults. Wm Beaumont GI Symposium, San Francisco, CA, Oct 1986

Schuchmann GD, Lee YTM: Changing Trends in Treatment of Anal Carcinoma. Wm Beaumont GI Symposium, San Francisco, CA, Oct 1986

Schuchmann GD, Barcia PJ: Phosphate Absorption after Fleet's Enema Administration in Adults. USUHS Day, Resident Paper Competition, Bethesda, MD, Apr 1987

Schuchmann GD, Lee YTM: Needle Localization Breast Biopsy Study. Gary P Wratten Surg Symposium, El Paso, TX, Apr 1987

Souliere C: Head and Neck Major Defect Reconstruction. Soft Tissue Surgery Workshop, TAMC, Jan 1987

Thomas RS, Wilkinson GR, Jones GP: Aneurysms of the Sinus of Valsalva in Micronesians. USUHS 5th Cardiothoracic Symposium, Bethesda, MD, Apr 1987

Tippets DD: Femoral Lengthening and Shortening. 1987 Hawaii Orthopaedic Association Spring Symposium, Honolulu, HI, Jun 1987

Whitman CS, Uribe JW: Acute Shoulder Dislocation Anatomic Pathology. 33rd Ann Meeting of the Orthopaedic Research Society, San Francisco, CA, Jan 1987

Wikert GA, Kreder KJ, Dresner ML: A New Method for Cystine Stone Lithotripsy. Western Section AUA Meeting, Kona, HI, Feb 1987

Wikert GA, Kreder KJ, Dresner ML: A New Technique for Cystine Stone Lithotripsy. American Association National Meeting Round Table Competition, Anaheim, CA, May 1987

Yim DWS: External (Combination) Rhinoplasty: Access to the Problem Nasal Deformity. American of Otolaryngology-Head and Neck Surgery Ann Meeting, Chicago, IL, Sep 1987

Yim DWS: Open Rhinoplasty Technique. Nasal Seminar, TAMC, Jan 1987

Yoshida GY, Antoine GA: Cutaneous Melanoma of the Head and Neck: The Tripler Army Medical Center Experience. Pacific Coast Oto-Ophthalmological Society, Seattle, WA, Jul 1987

Zieske LA: Orbital Dermoid/Lateral Orbitotomy. American Academy of Otolaryngology-Head and Neck Surgery Ann Meeting, Chicago, IL, Sep 1987

Zieske LA: Rhytidectomy Approach for Parotidectomy. Western Section Meeting American Academy of Facial Plastic and Reconstructive Surgery, Los Angeles, CA, Jan 1987

Zieske LA: Facial Complications of Sinusitis Head and Neck Trauma. Critical Care Conference, Pacific Institute of Continuing Medical Education, Kauai, HI, Mar 1987

Zieske LA: Nasal Anatomy. Nasal Surgery Seminar, TAMC, Jan 1987

Zieske LA: Panel/Case Discussions. Nasal Surgery Seminar, TAMC, Jan 1987

Zieske LA: Local Anesthetics. Soft Tissue Surgery Workshop, TAMC, Jan 1987

Zieske LA: Excisions and Repairs Around the Ear. Soft Tissue Surgery Workshop, TAMC, Jan 1987

### Detail Summary Sheet

Prot No: 22H80	Status: Terminated
TITLE: Antidiuretic Hormone Secretion in the Asphyxiated Neonate	
Principal Investigator: John R. Claybaugh, Ph.D.	
Associate Investigators: CPT Stephen R. Pratt	
Department/Section: Clinical Investigation/Physiology	
Key Words: antidiuretic hormone; asphyxiated neonate; cerebrospinal fluid; urine	
Funding: FY 86: 0    FY 87:	Periodic Review Date: Sep 87
Gifts: None	Decision: Terminate

OBJECTIVE: To determine the physiologic response of antidiuretic hormone (ADH) secretion in cerebrospinal fluid (CSF) and plasma in the newborn infant who has experienced central nervous system (CNS) injury, hypoxemia and asphyxia, i.e., is there evidence for independent control of release of ADH into the CSF and plasma. Also, to test the hypothesis that hypoxemia will increase release of ADH into the CSF and consequently lead to increased pressure in the CSF or other evidence of cerebral edema.

TECHNICAL APPROACH: Subjects will be neonates admitted for evaluation of sepsis, as well as all newborn infants with intracranial hemorrhage, CNS injuries from birth trauma, and neonates experiencing severe asphyxia with hypoxemia, increased intracranial pressure, and cerebral edema. On admission, each patient's APGAR scores, temperature, heart rate, blood pressure, and weight will be recorded. Arterial blood gases will be evaluated for acidosis, hypoxemia, and oxygen requirement. Spinal fluid will be collected for ADH assay, Na<sup>+</sup> and K<sup>+</sup> concentration, and osmolality. Urine will be assessed for creatinine, Na<sup>+</sup>, K<sup>+</sup>, osmolality, and ADH concentration. The data collected will be assessed to determine the correlation of CSF ADH and urinary ADH excretion and the correlations of both of these parameters to known stimulators of ADH release, i.e., plasma osmolality (if available), CSF osmolality, body temperature, and arterial blood pressure and PaO<sub>2</sub> and PaCO<sub>2</sub>. If computerized axial tomography scans are performed, an attempt will be made to correlate cerebral edema with high CSF ADH levels.

PROGRESS: No. of Subjects Enrolled - To Date:                      Reporting Period: 0

This protocol is terminated at the request of the principal investigator for the following reasons: This study will require a new consent form due to restrictions in neonatal research. Also, since Tripler AMC has recently joined Kapiolani Childrens' Hospital in the training of two neonatal fellows, these fellows have rewritten the protocol for resubmittal to carry out these experiments and, in addition, to include a comparison of CSF (ADH) in Viral and Bacterial Meningitis.

### Detail Summary Sheet

Prot No: 51H85	Status: Ongoing
TITLE: Altitude Sickness in Soldiers at 4200 Meters (Mauna Kea IV)	
Principal Investigator: John R. Claybaugh, Ph.D.	
Associate Investigators: Y. C. Lin, Ph.D.; CPT B. J. Freund, MC	
Department/Section: Clinical Investigation/Physiology	
Key Words: high altitude; exercise; mineralocorticoid supplementation; acetazolamide therapy; lung water; water and electrolyte balance; ophthalmology	
Funding: FY 86 \$300. FY 87: None	Periodic Review Date: Sep 87
Gifts: USAMRDC grant requested	Decision: Continue

**OBJECTIVE:** (1) Does exercise increase the vulnerability to acute mountain sickness (AMS) and complications? (2) Does acetazolamide (AZ) decrease the vulnerability of exercising soldiers to AMS at altitude? (3) Does AZ protect soldiers from exercise-induced fluid accumulation in the lung at high altitude? (4) Does AZ affect the hormonal responses to exercise and the 24-hour hormonal and water and electrolyte parameters? (5) Does the normally occurring decrease in aldosterone at high altitude have an effect on the occurrence of AMS, accumulation of lung water, and water and electrolyte balances? (6) Does high altitude exposure with no treatment differ from AZ or mineralocorticoid-treated subjects in ophthalmic measurements?

**TECHNICAL APPROACH:** Twenty-four subjects will be divided into three groups: group 1 = no treatment, group 2 = AZ pretreatment, group 3 = mineralocorticoid treatment. All subjects will run two hours per day at 4,100 M for 7 consecutive days. Twenty-four-hour urine will be collected throughout, as well as occasional pre- and postexercise blood samples.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

In order to conduct this study, additional supplies and temporary personnel are required. Therefore, request for a grant to USMRDC was submitted. Funding was not granted on this submittal. The verbal feedback we obtained indicated that the grant request, which was for these studies, should have been for only one study. Therefore, we may resubmit this request for a study to be conducted during the summer of 1988.



Detail Summary Sheet

Prot No: 41A86	Status: Ongoing
TITLE: Effects of Elevated Mineralocorticoid on Blood Pressure, Thirst, and Vasopressin Responses to Angiotensin in the Goat	
Principal Investigator: John R. Claybaugh, Ph.D.	
Associate Investigators: CPT Beau J. Freund, MS	
Department/Section: Clinical Investigation/Physiology	
Key Words: mineralocorticoid; vasopressin; angiotensin	
Funding: FY 86: \$3,000. FY 87:	Periodic Review Date: Sep 87
Gifts: VA/DOD Grant Pending	Decision: Continue

OBJECTIVE: To determine if the vasopressin (VP) response to angiotensin II is enhanced by previous administration of aldosterone, and whether the VP responses to central or peripheral administration of angiotensin II are differentially affected by the aldosterone treatment.

TECHNICAL APPROACH: Goats will be surgically prepared with chronic and indwelling lateral cannula in the third ventricle of the brain and a carotid arterial loop. After two weeks of aldosterone or vehicle injections, the responsiveness to angiotensin II will be determined. The angiotensin will be administered IV or into the lateral ventricle of the brain. The blood pressure, thirst, and CSF and plasma ADH responses will be determined.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Surgical procedures have been perfected and the responses to CSF administered angiotensin II have been measured in two trial protocols. We expect completion of this project in 12 months.

Detail Summary Sheet

Prot No: 44A86	Status: Ongoing
TITLE: Studies on the Effects of Calcium Entry Blockers in Experimental Adult Respiratory Distress Syndrome in Sheep	
Principal Investigator: COL Samuel A. Cucinell, MC	
Associate Investigators: Bert K.B. Lum, Ph.D.	
Department/Section: Clinical Investigation	
Key Words: calcium entry blockers; respiratory distress	
Funding: FY 86: \$300. FY 87:	Periodic Review Date: Sep 87
Gifts: None	Decision: Continue

OBJECTIVE: To determine if calcium entry blockers (CEBs) can prevent the pulmonary pathophysiology caused by endotoxin.

TECHNICAL APPROACH: Adult sheep will be chronically instrumented. The efferent duct of the caudal mediastinal lymph node will be cannulated for collection of pulmonary lymph. A chronic tracheostomy opening will be made for later insertion of a cuffed tracheostomy tube during experiments. A carotid loop will be created for measurement of arterial pressure and obtaining blood samples. After three weeks for surgical recovery, small (nonlethal) doses of endotoxin will be administered. Measurements will include lymph flow, lymph protein concentration, ratio of lymph to plasma protein concentration as indices of pulmonary permeability, dynamic compliance, airway resistance, cardiac output, heart rate, total peripheral resistance, arterial blood gases, and lung lymph thromboxane, prostacyclin, serum fibrin degradation products, and pulmonary clearances of platelets and white blood cells.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

This protocol has been inactive due to the departure of the principal investigator. The new Principal Investigator, MAJ Richard G. Kilfoyle, MC, Department of Surgery was assigned on 16 Sep 87.

## Detail Summary Sheet

Prot No: 26A87	Status: Ongoing
TITLE: Mechanism of Cold Induced Diuresis: a Pilot Protocol	
Principal Investigator: Margaret S. Dice, Biological Laboratory Technician	
Associate Investigators: John R. Claybaugh, Ph.D.; Aileen K. Sato; CPT Beau J. Freund, MS	
Department/Section: Clinical Investigation/Physiology	
Key Words: cold diuresis	
Funding: FY 86:	FY 87: Periodic Review Date: Jun 87
Gifts:	Decision: Continue

**OBJECTIVE:** This is a pilot protocol to develop the rat as a model for studying hormonal determinants of cold diuresis.

**TECHNICAL APPROACH:** To evaluate the diuretic response of conscious rats to low ambient temperatures - blood pressure, relevant blood and urinary hormones, and urine flows will be measured via indwelling catheters. Consequently, the development of methods for surgically implanting and maintaining bladder, and femoral arterial and venous catheters is the primary technical focus of this pilot.

**PROGRESS:** No. of Subjects Enrolled - To Date: 19      Reporting Period: 19

Nineteen animals have been surgerized to date. Surgical implantation of catheters has progressed to a satisfactory stage of ease and rapidity. Problems of catheter destruction by the animal have also been overcome.

### Detail Summary Sheet

Prot No: 47L86	Status: Completed
TITLE: Influence of Age on Volume Regulating Hormones and Fluid Shifts at Rest and During Prolonged Exercise	
Principal Investigator: CPT Beau J. Freund, MS	
Associate Investigators: Michael J. Buono, Ph.D.	
Department/Section: Clinical Investigation/Physiology	
Key Words: body fluids; exercise; age	
Funding: FY 86: \$300.	FY 87: Periodic Review Date: Sep 87
Gifts: None	Decision: Completed

OBJECTIVE: To examine the effects of aging on the fluid-regulating hormones and their response to prolonged exercise.

TECHNICAL APPROACH: Fourteen healthy, highly fit, male subjects will be recruited. Seven endurance-trained subjects aged 20-25, and seven subjects aged 50-60 years will be matched for training mileage and previous marathon performance. All subjects will be capable of running a marathon in less than 3 hr 15 minutes. All subjects will be given a complete physical and will undergo exercise stress test, including a 12-lead electrocardiogram. Blood and urine samples will be obtained before, during, and following the race. All data will be analyzed using a two-way analysis of variance with repeated measures.

PROGRESS: No. of Subjects Enrolled - To Date: 14      Reporting Period: 0

This study was completed at San Diego State University on Oct 28, 1986. The samples have been analyzed and the statistics have been completed. We are presently writing a manuscript from these data. No Tripler patients or personnel were used as subjects. All subjects were recruited from San Diego State University which is the location of the human subject consent forms. Dr. Michael J. Buono, San Diego State University, served as co-investigator.

## Detail Summary Sheet

Prot No: 35H87	Status: Ongoing
TITLE: Osmotic Control of Vasopressin Release in Endurance Trained and Untrained Men	
Principal Investigator: CPT Beau J. Freund, Ph.D.	
Associate Investigators: John R. Claybaugh, Ph.D.	
Department/Section: Clinical Investigation	
Key Words: plasma vasopressin; plasma osmolality	
Funding: FY 86: NA	FY 87: Periodic Review Date: Jul 87
Gifts: None	Decision: Continue

**OBJECTIVE:** The purpose of this study is to determine if chronic endurance exercise training alters the regulation of plasma vasopressin by examining the relationship of this hormone to changes in plasma osmolality.

**TECHNICAL APPROACH:** Seven endurance trained and 7 sedentary subjects will be infused with a 0.45% NaCl and/or a D5W (glucose) solution following 16 hours of dehydration. Blood pressure, plasma electrolytes, osmolality, and fluid regulating hormones including vasopressin, atrial natriuretic factor, aldosterone, and plasma renin activity will be measured at various time intervals. By altering plasma osmolality and then measuring the vasopressin response, the threshold and sensitivity of vasopressin to changes in osmolality can be assessed.

**PROGRESS:** No. of Subjects Enrolled - To Date: 12      Reporting Period: 12

The initial cardiovascular screening and descriptive data including maximal oxygen consumption, maximal and resting heart rate, minute ventilation, body weight and relative body fat have all been determined. Subjects will report to the laboratory on one additional occasion for the fluid infusion portion of the protocol.

No adverse effects have been noted or reported.

### Detail Summary Sheet

Prot No: 38A83	Status: Terminated
TITLE: The Use of Monoclonal Antibody to a <u>Pseudomonas</u> Ribosomal Protein Antigen for Passive Immunization Against <u>P. aeruginosa</u>	
Principal Investigator: MAJ Michael M. Lieberman, MS	
Associate Investigators:	
Department/Section: Clinical Investigation/Microbiology	
Key Words: monoclonal antibody; <u>Pseudomonas aeruginosa</u>	
Funding: FY 86: \$1,000. FY 87:	Periodic Review Date: Sep 87
Gifts: None	Decision: Terminate

**OBJECTIVE:** To determine whether monoclonal antibody to a Pseudomonas ribosomal protein antigen can protect mice by passive immunization against challenge with P. aeruginosa.

**TECHNICAL APPROACH:** Monoclonal antibodies are prepared by mixing immune spleen cells and myeloma cells in the presence of polyethylene glycol, resulting in a fusion of the two cell types. The fused cells, termed "hybridomas" since they are a hybrid of two different cells, have the myeloma cell properties of indefinite replication and of synthesizing only one particular immunoglobulin, but the immunoglobulin they synthesize is the antibody produced by the particular spleen cell that was fused. All monoclonal antibody preparations will be tested for antibodies to both protein and LPS antigens, and those preparations showing antibody activity to protein antigen only will be tested for passive mouse protection. Preparation of Pseudomonas ribosomal vaccines and passive mouse protection experiments will be performed as previously described.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

The study has been terminated due to the PCS of the principal investigator.

### Detail Summary Sheet

Prot No: 5A84	Status: Terminated
TITLE: Cellular Immunity Against <u>P. aeruginosa</u> Derived from Immunization of Mice with a <u>Pseudomonas</u> Ribosomal Vaccine	
Principal Investigator: MAJ Michael M. Lieberman, MS	
Associate Investigators:	
Department/Section: Clinical Investigation/Microbiology	
Key Words: cellular immunity; <u>Pseudomonas</u> <u>aeruginosa</u> ; ribosomal vaccine	
Funding: FY 86: \$2,000. FY 87:	Periodic Review Date: Sep 87
Gifts: None	Decision: Terminate

**OBJECTIVE:** (1) To determine whether the immune response to the Pseudomonas ribosomal vaccine includes cellular elements capable of protection upon transfer to nonimmune animals (adoptive immunity). (2) To determine whether vaccinated mice rendered leukopenic are still protected against infection. (3) To assess the importance of complement (specifically C5) to protection in vaccinated mice.

**TECHNICAL APPROACH:** A. Adoptive Immunity: Mice are immunized with the vaccine (20 per group). Spleens are excised from immunized mice and spleen cell suspensions prepared. (Spleen cell suspensions are also prepared from saline-administered mice.) Graded doses of immune and control spleen cells (from saline-administered mice) are injected (I.P.) into nonimmune mice (10 per group). Three days after injection of spleen cells, the mice are challenged with live cultures of P. aeruginosa. Challenged mice are scored for survival. Groups of mice receiving immune or control cells are compared.

B. Challenge of immune leukopenic mice: Mice are immunized with the vaccine (10 per group). Cyclophosphamide is administered to both immune and control mice, 5 days, 3 days, and 1 day prior to challenge. (Peripheral blood leukocyte counts will be made.) Mice are then challenged with live culture of P. aeruginosa. Challenged mice are scored for survival, comparing immune and control leukopenic mice. In addition, mice that were immunized but not rendered leukopenic, as well as nonimmune (control), nonleukopenic mice will be challenged as above. Thus, the efficacy of the vaccine in nonleukopenic mice will be compared to that in leukopenic mice.

C. Challenge of immune, C5 deficient mice. Mice that have a genetic defect resulting in a deficiency in complement (C5), as well as control mice, will be used in vaccination and challenge experiments as described above.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

The study has been terminated due to the PCS of the principal investigator.

Detail Summary Sheet

Prot No: 34A85	Status: Terminated
TITLE: Animal Usage for Phase I Clinical Trial of a <u>Pseudomonas aeruginosa</u> Ribosomal Vaccine (reference protocol 29H/85)	
Principal Investigator: MAJ Michael M. Lieberman, MS	
Associate Investigators: Sanford Berman, Ph.D.; COL Joel Brown, MC	
Department/Section: Clinical Investigation/Microbiology	
Key Words: <u>Pseudomonas aeruginosa</u> ; ribosomal vaccine; clinical trial	
Funding: FY 86: \$500. FY 87:	Periodic Review Date: Sep 87
Gifts: None	Decision: Terminate

OBJECTIVE: (1) Potency testing of vaccines to be used in the clinical trial; (2) testing of the sera collected from vaccinated volunteers for passive mouse protection.

TECHNICAL APPROACH: (1) Potency testing of vaccines to be used in the clinical trial was performed by active and passive immunization of mice followed by challenge with live P. aeruginosa. (2) Testing of the sera collected from vaccinated volunteers will be performed by passive immunization of mice followed by challenge with live P. aeruginosa.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

The study has been terminated due to the PCS of the principal investigator.



## Detail Summary Sheet

Prot No: 26A86	Status: Ongoing
TITLE: The Effect of Acetazolamide on Plasma and Cerebrospinal Fluid Antidiuretic Hormone (ADH) Concentrations in Conscious Goats During Acute Exposure to Simulated High Altitude	
Principal Investigator: Dr. John R. Claybaugh, Ph.D. Associate Investigators: CPT Beau J. Freund; Aileen K. Sato	
Department/Section: Clinical Investigation/Veterinary	
Key Words: high altitude; ADH; acetazolamide	
Funding: FY 86: \$1,500. Gifts: None	FY 87: \$300. Periodic Review Date: Sep 87 Decision: Continue

**OBJECTIVE:** To establish a conscious goat model for studying the effects of simulated high altitude hypoxia and to determine if the drug, acetazolamide, is effective in preventing the increased concentrations of ADH observed in cerebrospinal fluid as a result of acute exposure to simulated high altitude.

**TECHNICAL APPROACH:** Six adult female goats will be surgically prepared with a chronic tracheostomy, exteriorized carotid loop, and chronic implantation of a stainless steel guide tube over the cisterna magna. The goats will then be allowed to recover for at least four weeks after surgery. Each goat will undergo four experiments: (1) normoxia (sea level), (2) normoxia with ACZ pretreatment, (3) hypoxia (simulated high altitude), and (4) hypoxia with ACZ pretreatment. ACZ pretreatment will consist of 250 mg ACZ given orally b.i.d. for 72 hours prior to hypoxia/normoxia. Hypoxic gases will be administered via a cuffed tracheostomy tube. CSF, plasma, and urine samples are analyzed for arginine vasopressin, osmolality, electrolytes, and other hormones and other measurements including blood pressure, blood gases, and respiratory parameters.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Three goats successfully completed all four protocols. The results indicate that the plasma vasopressin response to hypoxia is transient. That is, during the six hours of continuous exposure to have 7% O<sub>2</sub>, plasma vasopressin concentration was significantly elevated during the first and second hours and then returned to baseline despite continued hypoxia and similar blood gas profiles. Acetazolamide had no effect on the response. CSF concentrations of vasopressin were only elevated during the second hour 7% O<sub>2</sub> without acetazolamide treatment experiments, but were not significantly different from the other experimental protocols. Results have been published in the abstracts for the 71st FASEB meetings, Washington, D.C., 1987.

### Detail Summary Sheet

Prot No: 17A84	Status: Completed
TITLE: The Hormonal Control of Amniotic Fluid Volume	
Principal Investigator: Catherine F. T. Uyehara	
Associate Investigators: John R. Claybaugh, Ph.D.	
Department/Section: Clinical Investigation/Physiology	
Key Words: amniotic fluid; vasopressin; vasotocin; osmolality	
Funding: FY 86: \$2,500. FY 87:	Periodic Review Date: Sep 87
Gifts: None	Decision: Completed

**OBJECTIVE:** To assess the endocrine regulation of amniotic fluid (AF) volume and composition during the 2d and 3d trimesters of gestation. To (1) document the levels of vasopressin (ADH), prolactin (PRL), cortisol (CORT), and aldosterone (ALDO) throughout gestation; (2) determine whether there is a correlation between AF osmolality and ADH/PRL/CORT/ALDO concentration; (3) determine whether there is a correlation between AF volume and ADH/PRL/CORT/ALDO levels.

**TECHNICAL APPROACH:** Baseline study: AF from fetuses during the 2d and 3d trimesters of gestation were obtained for baseline values. The samples were analyzed for osmolality, Na, K, CORT, VP, and VT. (We were unable to measure guinea pig PRL and ALDO levels with the assay kits available.) Hormone levels are obtained by radioimmunoassay of unextracted samples. In vivo AF volume experiments: Guinea pigs in the 3d trimester were used to set up experiments in which the effect of VP and VT on AF osmolality and volume can be studied. An initial sample of AF is immediately replaced with inulin in artificial amniotic saline which is mixed in with the remaining AF. A second sample is then obtained for inulin measurements used to estimate AF volume. Either a control of normal rabbit serum, VP and VT standard, or antisera to VP and VT is injected. After one hour, PAH is injected and a final sample is taken for volume estimation with this 2nd marker.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA  
Baseline study: Na concentration decreases and cortisol levels increase with gestational age in similar patterns to those seen with human measurements. Osmolality is constant and K increases in contrast to human results. Our VP and VT patterns in the 3d trimester agree with those seen in human AF: VP is constant and VT decreases. Hormone changes during the guinea pig's rapid development in the 3d trimester coincides with those seen in the 2d and 3d trimesters of human gestation. AF volume experiments: Inulin and PAH have been used to estimate AF volume. Both markers provide reasonable volume estimations only after complete mixing within the entire amniotic compartment is achieved, approximately one hour after injection. AF volumes in the third trimester range between 9 and 24 mls. We have estimated the AF turnover time in one set of fetuses to be about 18-20 hours. In studying the effect of exogenous VP and VT on AF volume regulation, we have not been able to measure the total amount of hormone injected into the AF. In fact, we have been able to account for less than 50% one hour after injection. We suspect that VP may be metabolized in the amniotic compartment and thus have submitted protocol 11A87 to study this problem.

Baseline study results were presented at the 1985 FASEB meetings at Los Angeles, CA, April 1985. Results have been included in a thesis "Metabolism of Vasopressin in the Fetal Guinea Pig Amniotic Sac", C.F.T. Uyehara.

Detail Summary Sheet

Prot No: 37A86	Status: Ongoing
TITLE: Preparation of a Vasotocin-Specific Antiserum in New Zealand White Rabbits for the Development of a Radioimmunoassay	
Principal Investigator: Catherine Uyehara	
Associate Investigators: John R. Claybaugh, Ph.D.; Aileen K. Sato	
Department/Section: Clinical Investigation/Physiology	
Key Words: vasotocin-specific antiserum	
Funding: FY 86: \$300.	FY 87: Periodic Review Date: Sep 87
Gifts: None	Decision: Continue

OBJECTIVE: To develop a radioimmunoassay for the measurement of vasotocin by preparation of a vasotocin-specific antiserum.

TECHNICAL APPROACH: A conjugation of VT bovine thyroglobulin and carbodiimide is prepared, diluted with 0.9% saline, and then emulsified with Freund's complete adjuvant. One ml of this solution is injected SQ over the dorsal thoracic and lumbar areas 5 times at 10-day intervals. Approximately one week later the rabbit is bled via an ear artery to test for a sufficient antiserum titer level. Booster shots are given at 10-day intervals until a sufficient antiserum titer level is attained. At this point, a 100 ml of whole blood is drawn by cardiac puncture while the animal is under Ketamine anesthesia. The animal is then euthanatized by injection of T-61.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

All immunizations have been completed. The rabbits bled and sacrificed the characterization the antiserum is presently under way. Ms. Uyehara will be replaced as PI because she is leaving. The new principal investigator is John R. Claybaugh, Ph.D.

# Detail Summary Sheet

Prot No: 11A87 Status: Ongoing

TITLE: The Metabolic Clearance of Arginine Vasopressin in the Amniotic Sac of the Fetal Guinea Pig

Principal Investigator: John R. Claybaugh, Ph.D.  
(formerly: Catherine F.T. Uyehara)

Associate Investigators: MAJ Gerard Letterie, Aileen K. Sato, Linda Kullama

Department/Section: Clinical Investigation

Key Words: arginine vasopressin

Funding: FY 86: NA FY 87: \$2,000. Periodic Review Date: Oct 87  
Gifts: Decision: Continue

**OBJECTIVE:** To demonstrate that the amniotic sac is a major site of fetal AVP clearance. Further, we will determine where in the amniotic sac AVP metabolism occurs (via amniotic fluid enzymes and/or via amniotic membrane receptors), explore the kinetics of this metabolic process, and characterize the metabolites produced.

**TECHNICAL APPROACH:** Vasopressin, either unlabelled or labelled with tritium-will be injected into the amniotic sac while the maternal guinea pig is under anesthesia and the fate of the vasopressin relative to insulin will be assessed by HPLC and radioimmuno assay. In vitro experiments will be conducted to determine the sites of vasopressin metabolism and action.

**PROGRESS:** No. of Subjects Enrolled - To Date: Reporting Period:

Pregnant guinea pigs have been used to date in these studies. It has been determined that vasopressin is metabolized in the amniotic sac into two components. One of the metabolites is des-gly-vasopressin and is formed by the action of a trypsin-like enzyme on vasopressin. This enzyme is located in the amniotic fluid; its source is presently unknown. The other product is not yet identified, but processes a phenylalanine amino acid and therefore is comprised, in part, by the "ring" portion of the vasopressin molecule. Studies on vasopressin action have demonstrated no effect in vivo on amniotic fluid osmolality or in vitro on membrane potential determined with an Ussing Chamber System. In fact, the guinea pig amniotic membrane has a nearly undetectable, electrical potential difference. Further studies are being done. Ms. Uyehara will be replaced as PI since this work has been written into her thesis and she will receive her Ph.D. and relocate. The new principal investigator is John R. Claybaugh, Ph.D.

### Detail Summary Sheet

Prot No: 27A87	Status: Ongoing
TITLE: Earliest Optimal Prosthetic Loading Time for IMZ, Titanium Sprayed, Implants In the Mandible and Maxilla of Goats	
Principal Investigator: MAJ Jeffery Dootson, DC	
Associate Investigators: COL Richard A. Kraut, DC; LTC Harvey Kessler, DC	
Department/Section: Dentistry	
Key Words: prosthetic, titanium implants	
Funding: FY 86: NA	FY 87: Periodic Review Date: Jun 87
Gifts:	Decision: Continue

**OBJECTIVE:** To determine the time required to achieve histological evidence of osteointegration of sprayed titanium (IMZ) implants in the maxilla and mandible of adult edentulous goats.

**TECHNICAL APPROACH:** 18 adult goats have been rendered partially edentulous. After four months of healing, titanium implants and hydroxyapatite will be implanted in all four edentulated areas of each goat. The goats will be sacrificed at predetermined periods and the degree of integration of the implants determined.

**PROGRESS:** No. of Subjects Enrolled - To Date: 18      Reporting Period: 18

All 18 goats have survived the edentulation phase of the project. Two goats were radiographed three months following edentulation, and based on their rate of healing, it is anticipated that the implants will be placed four months following edentulation (end of November, early December 1987).

Project is on schedule and all experimental material should be obtained by 1 June 1988.

Detail Summary Sheet

Prot No: 41H85	Status: Ongoing
TITLE: Comparison of Sublimaze Citrate in Intravenous Conscious Sedation for Outpatient Oral Surgery	
Principal Investigator: COL Richard A. Kraut, DC	
Associate Investigators:	
Department/Section: Dentistry/Oral Surgery	
Key Words: oral surgery; conscious sedation	
Funding: FY 86: \$300. FY 87:	Periodic Review Date: Aug 87
Gifts: None	Decision: Continue

**OBJECTIVE:** To compare the blood pressure, pulse, respiratory rate, PtcO<sub>2</sub> and PtcCO<sub>2</sub> in patients sedated with sublimaze versus sufentanil citrate for surgical removal of impacted wisdom teeth.

**TECHNICAL APPROACH:** Fifty consecutive volunteer ASA I patients who present to the Oral Surgery Clinical requiring removal of at least one maxillary and one mandibular impacted wisdom tooth and who request intravenous sedation will constitute the study group. Twenty-five patients will be randomly selected for each of the two study groups. Management will be the same for the two groups except that Group A patients will be sedated with sublimaze and diazepam. Group B patients will be given sufentanil citrate. Descriptive statistical analysis of blood pressure, pulse, respiratory rate, PtcO<sub>2</sub> and PtcCO<sub>2</sub> will be carried out.

**PROGRESS:** No. of Subjects Enrolled - To Date: 50      Reporting Period: 50

All 50 patients have been treated without complication. Data has just been analyzed. Final report will be completed by 1 December 1987.

### Detail Summary Sheet

Prot No: 10H86	Status: Ongoing
TITLE: Osteointegrated Implants Coated with Hydroxylapatite in the Treatment of Edentulous Jaws	
Principal Investigator: COL R. A. Kraut	
Associate Investigators: LTC Dennis R. Skirvin, DC; LTC Kenneth J. Juhar, DC; MAJ Alan F. Shernoff, DC	
Department/Section: Dentistry	
Key Words: edentulous mandibles; implants	
Funding: FY 86: \$300.	FY 87: Periodic Review Date: Nov 87
Gifts: None	Decision: Continue

**OBJECTIVE:** To determine the biocompatibility and prosthetic effectiveness of hydroxylapatite-coated osteointegrated implants in edentulous mandibles and to determine patient satisfaction with implant-stabilized mandibular dentures.

**TECHNICAL APPROACH:** Ten adult patients meeting the protocol criteria will be enrolled. Patients will undergo the placement of four to six osteointegrated implants while under local anesthesia and IV sedation. AP and lateral cephalometric radiographs and panographs will be obtained to determine the size and location of the implants. The implants will be exposed and loaded after three months of osteointegration. Upon placement of the transoral component of the implant, the prosthodontist will fabricate an implant supported and retained mandibular denture. Biocompatibility will be assessed by implant survival, panographic radiographs, and periodontal evaluation. Patient satisfaction will be assessed via a questionnaire at 1 and 10 months after insertion.

**PROGRESS:** No. of Subjects Enrolled - To Date: 10      Reporting Period: 10

All ten patients are progressing satisfactorily. Protocol dictates termination of project and preparation of final report when all patients have been wearing the prostheses for one year. This will occur in November 1987. Final report is anticipated by February 1988.

### Detail Summary Sheet

Prot No: 14H86	Status: Terminated
TITLE: Determination of $PO_2$ and $PCO_2$ Changes Associated with the Use of a Buccal Airway Device	
Principal Investigator: COL Richard A. Kraut Associate Investigators:	
Department/Section: Dentistry	
Key Words: orthognathic surgery	
Funding: FY 86: \$500.    FY 87:	Periodic Review Date: Nov 86
Gifts: None	Decision: Terminate

**OBJECTIVE:** To determine the effect of placement of a buccal airway on the  $PO_2$  and  $PCO_2$  in the postoperative management of patients in intermaxillary fixation.

**TECHNICAL APPROACH:** Patients will be divided into two study groups. Group A patients will undergo mandibular surgery. Group B will undergo maxillary surgery. Within each group a crossover will exist, in that alternate patients will have their  $PtcO_2$  and  $PtcCO_2$  determined first with the buccal airway present and then have the buccal airway removed. At completion of surgery, patients will be transported to the recovery room with endotracheal tube in place. While awaiting extubation, patients will breath 40% oxygen via a T-tube at a flow rate of 10 liters per min. Transcutaneous oxygen and carbon dioxide sensors will be applied to the patient's right midclavicular line just below the clavicle. When the patient has met standard criteria for extubation, a member of the Oral and Maxillofacial Surgery Service will annotate the patient's transcutaneous record and will monitor the patient for 15 minutes following extubation with or without a buccal airway in place. At the end of 15 minutes, either a buccal airway will be placed or the buccal airway will be removed. During the post-extubation period, the patient will receive 40% oxygen, 10 liter flow per minute, delivered via a face tent.

**PROGRESS:** No. of Subjects Enrolled - To Date: 18    Reporting Period: 18

Eighteen subjects have been completed without morbidity. The data has been analyzed and there are no statistical differences between the control patients without the airway and those with the airway.

Based on the lack of difference between the experimental group and the control, terminated by investigator.



### Detail Summary Sheet

Prot No: 45H86	Status: Completed
TITLE: A Comparison of Respiratory Depression of Diazepam and Midazolam in Intravenous Conscious Sedation for Outpatient Oral Surgery	
Principal Investigator: LTC Stephen H. Sutley, DC	
Associate Investigators:	
Department/Section: Dentistry/Oral Surgery	
Key Words: respiratory depression	
Funding: FY 86: \$300.	FY 87: Periodic Review Date: Sep 87
Gifts: None	Decision: Completed

OBJECTIVE: To compare the respiratory depression seen in patients treated with intravenous midazolam with the respiratory depression seen in patients treated with diazepam.

TECHNICAL APPROACH: Fifty ASA I patients requiring removal of at least one maxillary and one mandibular impacted wisdom tooth will be randomized into the two study groups. The following monitors will be used: precordial stethoscope; Dinamap Model No. 845XT, vital signs monitor, which will generate a printed record of the patient's pulse and blood pressure at one-minute intervals; and a Hewlett Packard Model No. 78850A, transcutaneous O<sub>2</sub> monitor with an in-line recorder. Patients will be seated in the semisupine position in the dental chair and monitors will be applied. An indwelling intravenous cannula will be placed in the antecubital fossa. A fixed dose of fentanyl, 1 µg/kg, will be administered to patients in both groups prior to sedation with either 0.15 mg/kg midazolam or 0.3 mg/kg diazepam, utilizing a titration principle to early signs of lid ptosis and slurred speech. Lidocaine will then be administered to the sedated patient to anesthetize the surgical site. The indicated teeth will then be surgically removed. Monitoring will continue for a minimum of five minutes after completion of the surgery or until the patient is sufficiently alert to be disconnected from the monitors.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

All 50 patients have been treated per protocol. No adverse effects observed. Data has just been analyzed. Final report is anticipated by 1 January 1988.

### Detail Summary Sheet

Prot No: 31H86	Status: Ongoing
TITLE: The Incidence of Clinically Relevant IgE-Hypersensitivity to Mold Spores in Hawaii	
Principal Investigator: MAJ Robert E. Bowen, MC	
Associate Investigators: MAJ William F. Long, MC	
Department/Section: Medicine/Allergy-Immunology Service	
Key Words: mold spores	
Funding: FY 86: \$2,000.	FY 87: Periodic Review Date: Mar 87
Gifts: None	Decision: Continue

OBJECTIVE: To determine whether or not the recently developed extracts of the mold spores, Myxomycetes, Basidiomycetes, and imperfect fungi represent clinically significant aeroallergens in Oahu.

TECHNICAL APPROACH: Two hundred adult patients will be skin-tested for common Hawaiian aeroallergens. In addition, nine spore extracts will be tested. Prick testing will be done first using a template on the back to insure uniformity. This will permit comparison with the three whole body imperfects. At the completion, the data will be collated.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No report filed for FY87.

Detail Summary Sheet

Prot No: 29H85	Status: Terminated
TITLE: Phase I Clinical Trial of a <u>Pseudomonas aeruginosa</u> Ribosomal Vaccine	
Principal Investigator: COL Joel Brown, MC	
Associate Investigators: MAJ Michael M. Lieberman, MS, Sanford Berman, Ph.D.	
Department/Section: Medicine	
Key Words: clinical trial; <u>Pseudomonas aeruginosa</u> ; ribosomal vaccine	
Funding: FY 86: \$300.	FY 87: Periodic Review Date: May 87
Gifts: None	Decision: Terminate

**OBJECTIVE:** To assess the safety and immunogenicity of Pseudomonas aeruginosa ribosomal vaccines in human volunteers.

**TECHNICAL APPROACH:** Volunteers will be immunized with the P. aeruginosa ribosomal vaccine. At specified times subsequent to vaccination, blood will be drawn and the specific antibody titer of the immune serum will be determined by passive protection of mice (i.e., administration of the immune serum to mice followed by challenge of the mice with live P. aeruginosa.)

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

Project not approved by OTSG. Principal Investigator requested that project be dropped.

### Detail Summary Sheet

Prot No: 30H86	Status: Ongoing
TITLE: The Natural History of HTLV-III Infection and Disease in a United States Military Population	
Principal Investigator: COL Joel D. Brown, MC	
Associate Investigators: MAJ Robert Gates, MC	
Department/Section: Medicine/Infectious Disease Service	
Key Words: HTLV-III; AIDS; infection	
Funding: FY 86: \$300.	FY 87: Periodic Review Date: Mar 87
Gifts: None	Decision: Pending Funding

**OBJECTIVE:** To assess the impact of HTLV-III infection on military readiness by defining the natural history of infection in the general military population and to form a study cohort upon which subsequent studies can be built.

**TECHNICAL APPROACH:** Personnel with confirmed HTLV-III infection who agree to participate will receive standard evaluation, counseling, and referral of contacts. Information will be centralized in a common data base. Serum and CSF samples will be stored at WRAIR for future testing. Follow-up studies will be performed every six months.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

Funding probably not forthcoming.

## Detail Summary Sheet

Prot No: 8L87	Status: Ongoing
TITLE: Noncompliant Behavior Among Hemodialysis Patients: Relationship to Disturbances of the Renin-Angiotensin-Aldosterone, Antidiuretic Hormone, and Atrial Natriuretic Hormone Axes	
Principal Investigator: MAJ L. Harrison Hassell, MC	
Associate Investigators: John R. Claybaugh, Ph.D.; Arnold Siemsen, MD; Jon Streltzer, MD	
Department/Section: Medicine/Nephrology	
Key Words: hemodialysis patients	
Funding: FY 86:	FY 87:
Gifts: none	Periodic Review Date: Oct 86 Decision: Continue

**OBJECTIVE:** Designed to compare levels of plasma renin activity (PRA), aldosterone (PA), antidiuretic hormone (ADH), and human atrial natriuretic peptide (hANP) in compliant and noncompliant hemodialysis patients to those in both humans and experimental animals associated with stimulation of thirst and salt appetite. Abnormalities of these hormonal axes may provide inferential evidence of disturbances of thirst and salt appetite which may underlie noncompliant behavior.

**TECHNICAL APPROACH:** Hemodialysis patients have blood drawn before and after two consecutive hemodialysis treatments. Urine is collected in the interim to calculate residual renal function. Patients have been categorized according to pre-defined criteria of compliance as assessed by interhemodialytic weight gain. The study will evaluate relationships of normal abnormalities to compliant and noncompliant behavior.

**PROGRESS:** No. of Subjects Enrolled - To Date: 8      Reporting Period:

Adverse effects: No adverse effects have occurred. The study needs two more patients, one in each category, to be completed. The lab studies have been performed for all patients to date. Analysis of data pending complete enrollment of patients. None of this data has been published.

### Detail Summary Sheet

Prot No: 19H84	Status: Ongoing
TITLE: Treatment of Graves' Ophthalmopathy with Cyclosporin	
Principal Investigator: MAJ J. Craig Holland, MC	
Associate Investigators:	
Department/Section: Medicine/Endocrine-Metabolic	
Key Words: Graves' ophthalmopathy	
Funding: FY 86: 0	FY 87:
Gifts: None	Periodic Review Date: Jul 86
	Decision: Continue

**OBJECTIVE:** To assess the efficacy of Cyclosporin treatment on the ophthalmopathy of Graves' disease.

**TECHNICAL APPROACH:** This is a random crossover study comparing Cyclosporin therapy of Graves' ophthalmopathy versus the standard of current therapy, high-dose oral Prednisone. Because of potential toxicity, this is not a double-blind study. The drugs will be administered for three weeks each, and then the patient will be crossed over with clinical response measured by an ophthalmopathy index. There will be a pretherapy clinical assessment and the usual laboratory testing pre-, post-, and during therapy.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

Because of the departure of MAJ Holland, the protocol has been suspended until a new principal investigator is appointed. MAJ Holland has returned to TAMC and will resume the role of principal investigator for this study.

### Detail Summary Sheet

Prot No: 16H87	Status: Terminated
TITLE: Azidothymidine (AZT) Treatment of Persons with Acquired Immunodeficiency Syndrome (AIDS)	
Principal Investigator: Arthur C. Johnson, III., MD	
Associate Investigators: MAJ Robert Gates, MC	
Department/Section: Medicine/Infectious Disease	
Key Words: Azidothymidine, AIDS	
Funding: FY 86: NA	FY 87:
Gifts: none	Periodic Review Date: Dec 86 Decision: Terminate

OBJECTIVE: To participate in an investigational new drug (IND) exemption treatment protocol for AZT in the management of persons who have acquired immunodeficiency syndrome who meet the minimum criteria of having had an episode of Pneumocystis carinii pneumonia.

TECHNICAL APPROACH: Treatment of AIDS patients with Pc pneumonia will be treated on nationally approved AZT protocol. No procedures other than those required by the standard HIV-infected patient's evaluation and monitoring as appropriate for disease severity.

PROGRESS: No. of Subjects Enrolled - To Date: 2      Reporting Period: 2

Two subjects were enrolled in this study. One had been previously enrolled in the national treatment IND study at the time of entry into our clinical investigation project, and the other subject was begun on the drug at Tripler. The former patient tolerated the drug well but died from his underlying disease. The latter patient has required intermittent transfusions and drug withdrawals but currently has a satisfactory quality of life.

The national treatment IND was ended in March 1987 and the drug became available on a prescription basis, so the study was terminated without completion. No publications originated from this project.

### Detail Summary Sheet

Prot No: 2H86	Status: Ongoing
TITLE: Systolic Hypertension in the Elderly Program	
Principal Investigator: MAJ Victoria Rains	
Associate Investigators: Dr. J. David Curb	
Department/Section: Medicine	
Key Words: hypertension	
Funding: FY 86: \$300.	FY 87: Periodic Review Date: Oct 86
Gifts: None	Decision: Temporarily Suspended

**OBJECTIVE:** To assess whether long-term administration of antihypertensive therapy to elderly subjects with isolated systolic hypertension reduces the combined incidence of fatal and nonfatal stroke.

**TECHNICAL APPROACH:** The study will be a double-blind, placebo-controlled, randomized clinical trial. Half of the participants will be given active intervention using a step-up treatment program. The other half will be randomly assigned to placebo.

**PROGRESS:** No. of Subjects Enrolled - To Date: 9      Reporting Period: 9

No report filed for FY87. DF sent to Chief, Medicine requesting study be suspended until a new principal investigator is designated.



Detail Summary Sheet

Prot No: 33H86	Status: Ongoing
TITLE: Bone Loss in the Elderly. Ancillary Study to Systolic Hypertension in the Elderly Program	
Principal Investigator: MAJ Victoria Rains, MC	
Associate Investigators:	
Department/Section: Medicine	
Key Words: hypertension; bone loss; osteoporosis	
Funding: FY 86: \$300.	FY 87: Periodic Review Date: Mar 87
Gifts: Bone density determinations	Decision: Temporarily Suspended

OBJECTIVE: To determine what factors are involved in the development of osteoporosis and the effect of thiazide-like diuretics in retarding bone loss.

TECHNICAL APPROACH: Participants in this study will answer questions regarding potential risk factors for osteoporosis. Either clorthalidone or a placebo will be given to the patients. Dual photon densitometry of the spine and single photon densitometry of the dominant forearm, ulna, radius, dominant heel will be done at baseline, annually, and at completion of the project (4-6 years).

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No report filed for FY87. DF sent to Chief, Department of Medicine requesting study be suspended until a new principal investigator is designated.

### Detail Summary Sheet

Prot No: 35H86	Status: Completed
TITLE: Thymosin $\alpha$ -1 Levels in Chronic Hepatitis B Infection	
Principal Investigator: CPT Kenneth E. Sherman, MC	
Associate Investigators: Allan Goldstein, Ph.D.	
Department/Section: Medicine/General Medicine Svc.	
Key Words: hepatitis; infection	
Funding: FY 86: \$300.      FY 87:	Periodic Review Date: Apr 87
Gifts: None	Decision: Completed

**OBJECTIVE:** To determine whether thymosin  $\alpha$ -1 levels vary between chronic hepatitis B (HB) carriers, individuals who have cleared HB, and healthy individuals who have no evidence of HB infection.

**TECHNICAL APPROACH:** Approximately 100 patients will be divided into three groups (chronic HB carriers and two control groups: (a) persons who have been infected with HB and cleared the infection and (b) healthy uninfected individuals). Blood will be drawn for a series of tests. Serum samples will be frozen and shipped to the George Washington University Medical Center for testing of thymosin  $\alpha$ -1. Additional testing includes analysis for HBsAG, antiHBs, anti-HBc, HBeAg, anti-HBe, HTLV-III, and hepatic enzyme profile. Data will be analyzed.

**PROGRESS:** No. of Subjects Enrolled - To Date: 85      Reporting Period: 85

Study completed including addition of returning patients to measure helper suppression cell levels. Final manuscript to be submitted to Gastroenterology is attached for return and for final typing.

## Detail Summary Sheet

Prot No: 37H85	Status: Ongoing
TITLE: Nutritional Support of the Hospitalized Patient: A Comparison Between Continuous and Intermittent Administration of Enteral Tube Feedings	
Principal Investigator: 1LT Leslie R. Kalbach, AN	
Associate Investigators:	
Department/Section: Nursing	
Key Words: enteral tube feeding	
Funding: FY 86: \$500. FY 87:	Periodic Review Date: May 86
Gifts: None	Decision: Temporarily Suspended

**OBJECTIVE:** To ascertain which mode of tube feeding administration, intermittent or continuous, is optimal for the hospitalized patient in regard to maximizing the benefits of nutritional support and minimizing adverse reactions.

**TECHNICAL APPROACH:** Subjects for the study are selected from a surgical ward population of patients and must meet the criteria of being unable or unwilling to consume caloric needs by p.o. intake alone. Patients from both the otorhinolaryngology and neurosurgical services are considered and entered into the study if enteral tube feeding nutritional support is indicated, and patients are randomly assigned to either mode of administration. After one week of the initial mode of administration, the patient is changed to the alternate mode for another week. Data is collected by nursing staff responsible for the care of the patient per intake and output worksheets and study-specific data sheets. If patients demonstrate a desire to eat, they must be eliminated from the study.

**PROGRESS:** No. of Subjects Enrolled - To Date: 2      Reporting Period: 2

Principal Investigator has PCS'd. The study is suspended until the assignment of a new principal investigator.

### Detail Summary Sheet

Prot No: 32H86	Status: Completed
TITLE: Recovery Characteristics following Antagonism of Vecuronium with Edrophonium, Neostigmine and Pyridostigmine	
Principal Investigator: CPT Joseph Yungbluth, ANC	
Associate Investigators: CPT Donald T. Albee, ANC; CPT Jill D. Henry, ANC; CPT Kathleen McAnallen, ANC	
Department/Section: Nursing/Anesthesia and Operative Services	
Key Words: Vecuronium; reversal agents	
Funding: FY 86: \$300.	FY 87: Periodic Review Date: Mar 87
Gifts: Equipment (Loan)	Decision: Completed

**OBJECTIVE:** To determine if there is a difference in the reversal characteristics of Vecuronium when comparing reversal agents.

**TECHNICAL APPROACH:** A transducer to measure the force of muscular contraction will be placed on the wrist and thumb ring. Once sleep has been induced with anesthesia, two small needle electrodes will be placed just under the skin near the wrist. Measurement of muscular function will be obtained. Vecuronium will be administered through the IV. At the end of surgery, one of three reversal agents will be administered. Measurements of the return of muscular function will be recorded. After the final measurement has been taken, the needle electrodes will be removed. Statistical analysis will be performed to determine significant differences with the three reversal agents.

**PROGRESS:** No. of Subjects Enrolled - To Date: 54      Reporting Period: 6

The number of subjects enrolled were 54. The number of subjects reported on were 38. The conclusion was that edrophonium statistically reversed the neuromuscular blocking effects of vecuronium faster than prostigmine or pyridostigmine. No statistically significant differences existed between the groups regarding height, weight, age, doses of drugs employed. Differences did exist between the groups regarding heart rate and blood pressure changes and arrhythmics observed; however none were clinically significant. A manuscript is currently under consideration with the American Association of Nurse Anesthetists Journal.

# Detail Summary Sheet

Prot No: 17H86

Status: Terminated

TITLE: A Controlled Trial of Intrauterine Insemination for the Treatment of Infertility Due to Oligospermia

Principal Investigator: CPT John W. Byron

Associate Investigators: CPT Edward J. Ramirez

Department/Section: Obstetrics and Gynecology/Reproductive Endocrinology Svc

Key Words: infertility; oligospermia

Funding: FY 86: \$500 FY 87:

Periodic Review Date: Nov 87

Gifts: None

Decision: Terminate

OBJECTIVE: To determine if intrauterine insemination is an effective therapy for infertility caused by low sperm counts.

TECHNICAL APPROACH: Appropriately timed intrauterine insemination of husband's sperm will be alternated with natural coitus.

PROGRESS: No. of Subjects Enrolled - To Date: 6 Reporting Period: 6

A total of six subjects enrolled without success of pregnancy. It is now recognized that published data from other institutions clearly does not support this therapy. It is recommended that this study be terminated because of loss of co-investigator and needed equipment, and also due to the fact of new evidence published.

### Detail Summary Sheet

Prot No: 20H84	Status: Terminated
TITLE: Assessment of Prolactin, Vasopressin, Cortisol, and Aldosterone in Amniotic Fluid of Human Fetuses During Gestation	
Principal Investigator: CPT Mario Colavita	
Associate Investigators: John R. Claybaugh, Ph.D.; Catherine Uyehara; Aileen K. Sato; Bea Reeves; LTC R. S. Pumphrey, MC	
Department/Section: Obstetrics and Gynecology	
Key Words: vasopressin; vasotocin; aldosterone; cortisol; prolactin; amniotic fluid; osmolality; human gestational age	
Funding: FY 86: \$1,500. FY 87:	Periodic Review Date: Jan 87
Gifts: None	Decision: Terminate

**OBJECTIVE:** To correlate amniotic fluid osmolality, prolactin (PRL), vasopressin (ADH), cortisol (CORT), and aldosterone (ALDO) with age of gestation in the normal human fetus and to measure these hormones in conditions of abnormal amniotic fluid volume to determine if there is a possible underlying hormonal basis to the malfunction.

**TECHNICAL APPROACH:** The fetus has been shown to produce vasotocin in lower mammals. We began with the working hypothesis that vasotocin would be in measurable quantities in the amniotic fluid. The Physiology Service has developed an antisera to vasopressin that cross-reacts with vasotocin almost 100%, and other antisera that do not cross-react. Vasotocin concentration can then be determined by subtraction when these antisera are employed in radioimmunoassay. Other assays are ongoing in the Physiology Service. Amniotic fluid will be collected at two times. Both amniocenteses are a result of the necessity of other tests, i.e., assessment of genetic abnormalities (14-17 weeks) and fetal lung maturity (33-40 weeks). In addition, term amniotic fluid will be collected in conditions of polyhydramnios and oligohydramnios.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

Past principal investigators (Dr. Shah and Dr. Colavita) and co-investigator (Dr. Pumphrey) have left the department. Clinician's interest in this study is poor. Too many attempts were made for successful collection of the sample without success. This study is terminated due to departure of all investigators.

### Detail Summary Sheet

Prot No: 8H86	Status: Ongoing
TITLE: Infection Prevention in Patients Undergoing Radical Hysterectomy	
Principal Investigator: COL Kunio Miyazawa, MC (formerly: MAJ Enrique Hernandez, MC)	
Associate Investigators:	
Department/Section: Obstetrics and Gynecology/Gynecology Oncology Service	
Key Words: hysterectomy; antibiotics; infection	
Funding: FY 86: \$300.	FY 87: Periodic Review Date: Nov 87
Gifts: None	Decision: Continue

OBJECTIVE: To determine the effectiveness of antibiotics (cefamandole) in preventing infectious morbidity of radical abdominal hysterectomy.

TECHNICAL APPROACH: In a double-blind, randomized study patients receive placebo or iv cefamandole prior to the surgical incision and again two hours later.

PROGRESS: No. of Subjects Enrolled - To Date: 10      Reporting Period: 10

A total of 10 cases has been added to the study without clear evidence of increased morbidity in either group. COL Kunio Miyazawa, MC, is now principal investigator after departure of MAJ Hernandez. Due to limited case load, collection is not satisfactory. Recommend continuation of this study for an additional year to see if adequate numbers become available.

### Detail Summary Sheet

Prot No: 29T86	Status: Ongoing
TITLE: GYN-Surgical Training Laboratory Using Animal Models (Swine)	
Principal Investigator: COL Kunio Miyazawa, MC (formerly: MAJ Enrique Hernandez, MC)	
Associate Investigators:	
Department/Section: Obstetrics and Gynecology/Gynecology Oncology	
Key Words: training	
Funding: FY 86: \$500.	FY 87: Periodic Review Date: Sep 87
Gifts: None	Decision: Continue

**OBJECTIVE:** To expose TAMC gynecology residents to procedures performed in the management of gynecologic malignancies and to train them in the management of minor urologic and intestinal complications during gynecologic surgery.

**TECHNICAL APPROACH:** Pigs will be preanesthetized with Acepromazine, 0.2 mg/kg IM, and Atropine, 0.04 mg/kg IM; sedated with Ketamine HCl, 22 mg/kg IM; and then either (1) anesthetized with sodium pentobarbital iv to effect with additional pentobarbital given as needed to maintain a surgical plane of anesthesia, or (2) anesthesia induced with sodium pentothal and maintained with nitrous oxide and methoxyflurane. All animals will be intubated. All animals will be euthanatized at the end of the laboratory so no postoperative medication is necessary.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

Six sessions were held this fiscal year. The objectives were met. Still ongoing. COL Kunio Miyazawa, MC, has become the principal investigator after separation of MAJ Hernandez. It is strongly supported by OB-GYN residency review to continue this advanced technical animal research program for our trainees. Recommend continuation.



Detail Summary Sheet

Prot No: 17H87	Status: Ongoing
TITLE: Comparison of Pregnancy Rates Using Oil-based and Water-based Contrast Medium in the Evaluation of Tubal Patency	
Principal Investigator: MAJ Gerard S. Letterie, MC	
Associate Investigators:	
Department/Section: Obstetrics and Gynecology	
Key Words: tubal patency	
Funding: FY 86: NA	FY 87:
Gifts: None	Periodic Review Date: Feb 87
	Decision: Continue

**OBJECTIVE:** To determine if the use of oil-based contrast medium in the evaluation of tubal patency enhances fertility when compared to water-based solutions.

**TECHNICAL APPROACH:** Sixty patients fulfilling the study criteria will be entered into one of two random study groups. Group I patients will have an oil-based contrast medium injected during the intra-operative tubal insufflation and a water based contrast medium will be used in an identical fashion on Group II patients. Effectiveness will be determined by the conception rates for the two groups at the end of a three month period.

**PROGRESS:** No. of Subjects Enrolled - To Date: 8      Reporting Period: 8

Total of 8 cases entered up to now. Problem is related to finding a normal pelvis. The dates shows about 85 percent of patients are found to have abnormal pelvis. Will continue to accumulate data. Recommend continuation of this study.

### Detail Summary Sheet

Prot No: 6H86	Status: Ongoing
TITLE: Functional Renal Reserve and Early Detection of Renal Disease in Patients with Limited Joint Mobility and Diabetes Mellitus: A Cross-sectional Study	
Principal Investigator: LTC Richard A. Banks Associate Investigators:	
Department/Section: Pediatrics/Endocrinology	
Key Words: diabetes mellitus	
Funding: FY 86: \$500.      FY 87:	Periodic Review Date: Jan 87
Gifts: None	Decision: Temporarily Suspended

OBJECTIVE: To correlate the degree of renal involvement in patients with insulin dependent diabetes mellitus (IDDM) and limited joint mobility (LJM), using several tests of renal function and reserve.

TECHNICAL APPROACH: The current protocol is essentially unchanged except that five 30-minute urine samples are being obtained between 1 and 3 hours after the ingestion of meat, as opposed to the original two samples. This change was made to ensure detection of transient peaks of creatinine.

PROGRESS: No. of Subjects Enrolled - To Date:      Reporting Period:

This protocol was placed on a temporarily inactive status as requested by the principal investigator at the last semi-annual review, pending re-evaluation of the renal clearance determinations. At this time, the protocol is still in that status, and the principal investigator is deciding on a more reliable methodology for determination of GFR.

No new patients have been entered since the last review.

## Detail Summary Sheet

Prot No: 3H87	Status: Ongoing
TITLE: Serum Phosphate Levels in Necrotizing Enterocolitis of the Newborn	
Principal Investigator: LTC Richard A. Banks, MC	
Associate Investigators: COL Franklin Smith, MC; MAJ Robert Jarrett, MC; MAJ Lynn Whittington, MC	
Department/Section: Pediatrics	
Key Words: neonate, enterocolitis, necrotizing	
Funding: FY 86:	FY 87: Periodic Review Date: Oct 87
Gifts: none	Decision: Continue

OBJECTIVE: To evaluate the changes in serum phosphate concentrations in neonates with necrotizing enterocolitis (NEC) as a possible marker for the presence and extent of NEC.

TECHNICAL APPROACH: Serum phosphate determination in three groups of patients. NEC, maybe NEC, and not NEC.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No TAMC patients have entered into the study as of this time. The study is ongoing.

# Detail Summary Sheet

Prot No: 4H87	Status: Ongoing
TITLE: Immunosuppressive Therapy with Methylprednisolone, Prednisone, and Azathioprine in Patients with Newly Diagnosed Insulin-Dependent Diabetes Mellitus	
Principal Investigator: LTC Richard A. Banks, MC	
Associate Investigators: Janel Silverstein	
Department/Section: Pediatric	
Key Words: diabetes mellitus, pediatric, ketoacidosis	
Funding: FY 86:	FY 87: Periodic Review Date: Oct 87
Gifts: Imuran	Decision: Continue

OBJECTIVE: To prevent the progression of autoimmune destruction of the pancreatic islet  $\beta$ -cells in previously undiagnosed diabetic patients presenting with hyperglycemia but without overt ketoacidosis.

TECHNICAL APPROACH: Four randomly assigned treatment arms: 1) steroids and imuran 2) steroids 3) imuran and 4) neither steroids nor imuran; measured against multiple parameters of progression of diabetes.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No TAMC patients have met the criteria for entry into the study as of this time. The study is on-going.

## Detail Summary Sheet

Prot No: 31H85	Status: Ongoing
TITLE: Treatment of Kawasaki Syndrome with Intravenous Gamma Globulin	
Principal Investigator: COL James W. Bass, MC	
Associate Investigators: Marian E. Melish, M.D.	
Department/Section: Pediatrics	
Key Words: Kawasaki syndrome	
Funding: FY 86: \$300. FY 87:	Periodic Review Date: Jun 87
Gifts: IV Gamma Globulin	Decision: Continue

**OBJECTIVE:** In uncontrolled studies involving 70 patients in Japan, high dose (400 mg/kg/day) intravenous gamma globulin administered early in illness for 2-4 days has been reported to decrease the frequency of coronary aneurysms from approximately 20% (historical controls) to 3%. Because of severe methodologic flaws in Japanese studies, we propose a multicenter cooperative controlled trial of the possible benefits of this therapy.

**TECHNICAL APPROACH:** Children with Kawasaki Syndrome will be recruited into the study within the first 10 days of illness. After ascertainment of diagnosis, children will be randomized to receive I.V. gamma globulin or serve as controls without infusion. Follow-up will consist of repeated history and physical examinations, repeated echocardiograms and laboratory tests of hematology, liver and kidney function, coagulation, and immunology at entry, day 15, day 30, day 90, and one year after onset. Echocardiograms will be evaluated blindly by a committee of cardiologists from all participating centers. Angiograms will be performed on all patients with evidence of coronary aneurysms by echocardiogram or other tests.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

This is a cooperative study with Dr. Marian Melish of the Department of Pediatrics at the University of Hawaii School of Medicine. One patient, no adverse effects, the study is ongoing.

### Detail Summary Sheet

Prot No: 13H86	Status: Ongoing
TITLE: Calcium and Phosphorus Balance Studies in Low-Birth-Weight Infants Receiving Parenteral Alimentation	
Principal Investigator: MAJ Thomas J. Kueser	
Associate Investigators: MAJ Robert V. Jarrett; COL Franklin R. Smith	
Department/Section: Pediatrics/Neonatology Service	
Key Words: infants, low birth rate	
Funding: FY 86: \$300.	FY 87: \$300.
Gifts: None	Periodic Review Date: Nov 87 Decision: Continue

OBJECTIVE: To determine the pattern of calcium and phosphorus excretion and retention in premature infants receiving daily calcium and phosphorus by parenteral hyperalimentation.

TECHNICAL APPROACH: All infants will receive the standard regimen of hyperalimentation which provides calcium gluceptate and sodium phosphate, in addition to maintenance sodium chloride and potassium chloride. All infants will receive the recommended daily dose of Vitamin D. In addition, 24-hour urine collections for calcium, phosphate, sodium, and creatinine excretion will be obtained in 8-hour fractions (this is the only deviation from routine NICU procedure required in this study). Calcium and phosphorus accretion rates will be compared to the standard in utero accretion rates published in medical literature.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This project is still ongoing but no patients have been enrolled to this date. MAJ Lynn K. Whittington, MC is no longer one of the investigators.

## Detail Summary Sheet

Prot No: 21H86	Status: Ongoing
TITLE: Prophylactic Intravenous Sandoglobulin for Infections in High-Risk Neonates	
Principal Investigator: MAJ Thomas J. Kueser	
Associate Investigators: MAJ Robert Jarrett	
Department/Section: Pediatric/Neonatology Service	
Key Words: neonatal infection	
Funding: FY 86: \$300.	FY 87: Periodic Review Date: Dec 87
Gifts: Sandoglobulin	Decision: Continue

**OBJECTIVE:** To determine in a double-blind manner if the prophylactic use of intravenous immune serum globulin compared to an albumin placebo affects the morbidity or mortality of bacterial infections in high-risk neonates.

**TECHNICAL APPROACH:** Fifty consecutive infants meeting criteria for the protocol will be enrolled. The enrolled infants will receive a single IV infusion of either Sandoglobulin, 500 mg/kg, or placebo (albumin, 5 mg/kg). All infants will be monitored during infusion. Infants will be reevaluated on days 9 (postinfusion), 7, 14, and 56 with serum total IgG, opsonic antibody to GBS, physical examination, and documentation of coexisting disease, concomitant medications, antibiotic therapy, blood product transfusions, and the occurrence of septic episodes. Following the eight-week study period, blood collected for immunoelectrophoresis and historical data will be forwarded to WRAIR for evaluation.

**PROGRESS:** No. of Subjects Enrolled - To Date: 20      Reporting Period: 20

The project is ongoing. There has been 20 patients (aim for 50 patients) enrolled in the study to date. There have been no patients dropped/withdrawn from the study to date.

# Detail Summary Sheet

Prot No: 22H86	Status: Ongoing
TITLE: The Assessment of Pulmonary Function in Neonates with Severe Respiratory Distress Given Infusions of Intravenous Immunoglobulin for Suspected Sepsis	
Principal Investigator: MAJ Thomas J. Kueser	
Associate Investigators:	
Department/Section: Pediatrics/Neonatology	
Key Words: neonates; pulmonary function; sepsis	
Funding: FY 86: \$300.	FY 87: Periodic Review Date: Dec 86
Gifts: Sandoglobulin	Decision: Continue

**OBJECTIVE:** To determine in a controlled, double-blind manner if there are any changes in pulmonary function in neonates with severe respiratory distress after intravenous infusions of immunoglobulin for suspected sepsis.

**TECHNICAL APPROACH:** Fifty infants meeting the protocol criteria will be enrolled. Infants will receive a blinded administration of either intravenous immunoglobulin or albumin placebo. Ventilator support will be provided as indicated. Specific pulmonary functions will be monitored. Assessment of pulmonary function will be made prior to the intravenous infusion and 15 minutes, 1 hour, and 2 hours after the infusion, and the changes will be noted. The data obtained will be evaluated for possible correlation between intravenous immunoglobulin therapy and changes in pulmonary function by standard statistical methods.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

The project is still ongoing but as of this date no patients have been enrolled.



# Detail Summary Sheet

Prot No: 21H85	Status: Ongoing
TITLE: Efficacy of Cholestyramine in Acute Infantile Diarrhea	
Principal Investigator: CPT Michael Henrickson	
Associate Investigator: COL James W. Bass, MC	
Department/Section: Pediatrics	
Key Words: diarrhea, infantile	
Funding: FY 86: \$300. FY 87:	Periodic Review Date: Apr 87
Gifts: None	Decision: Temporarily Suspended

OBJECTIVE: To determine if cholestyramine reduces the frequency and duration of diarrhea in infants with diarrhea of less than 72 hours' duration.

TECHNICAL APPROACH: Infants 6 months to 2 years of age with diarrhea of less than 72 hours' duration will be randomized to receive either cholestyramine or a placebo for three days to be administered by the parents at home. A record of frequency and approximate volume of stools will be kept by the parents, and the patients will be followed in the pediatric clinic at 3-5 days and 2 weeks after initiation of therapy.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study is suspended because of PCS of principal investigator.

### Detail Summary Sheet

Prot No: 6H87	Status: Terminated
TITLE: Comparison of Rapid ELISA Test Versus Paired Concurrent Throat Cultures for the Diagnosis of Group A $\beta$ -Hemolytic Streptococcal Pharyngitis	
Principal Investigator: CPT Robert R. Wittler, MC	
Associate Investigators: COL James W. Bass, MC; CPT Lawton Seal, MS	
Department/Section: Pediatrics	
Key Words: streptococcal pharyngitis	
Funding: FY 86: NA	FY 87: Periodic Review Date: Nov 87
Gifts: Kits	Decision: Terminate

**OBJECTIVE:** To investigate the sensitivity, specificity, positive predictive value and negative predictive value of a commercially available enzyme-linked immunosorbant assay (ELISA) for the diagnosis of group A  $\beta$ -hemolytic streptococcal pharyngitis.

**TECHNICAL APPROACH:** After informed consent was obtained, patients who presented to the TAMC Pediatric Clinic with pharyngitis had triplicate (identical technique) throat swabs obtained. One swab was utilized for a group A strep ELISA detection assay. The other two swabs were labelled with random numbers and sent to the lab for routine culture. The sensitivity specificity of the ELISA technique was compared to the throat culture and the throat culture was also compared to the second throat culture.

**PROGRESS:** No. of Subjects Enrolled - To Date: 183 Reporting Period: 183

183 subjects were enrolled in the study. Subsequent to that the kits were no longer made available and the study was terminated.

Analysis of the results revealed the ELISA test to have a sensitivity of 58% compared to either TC, while the TC compared to the duplicate TC had a sensitivity of 84%. The specificity of the ELISA compared to the TC was 82%, while the TC compared to the duplicate TC was 97%.

Although we would have liked to enrolled 250-300 subject, it seemed that this ELISA techniques (Ventrescreen) was not accurate enough to replace the throat culture.

## Detail Summary Sheet

Prot No: 14H87	Status: Ongoing
TITLE: The Evaluation of Early Detection of Group A $\beta$ -hemolytic Streptococci and Treatment in Index Patients and Household Contacts	
Principal Investigator: CPT Robert R. Wittler, MC	
Associate Investigators: COL. James W. Bass, MC; CPT Lawton A. Seal, AN; CPT Denise M. Demers, MC	
Department/Section: Pediatrics	
Key Words: streptococcal infection	
Funding: FY 86: NA	FY 87: Periodic Review Date: Mar 87
Gifts: none	Decision: Continue

**OBJECTIVE:** To investigate the potential benefit of early detection and treatment in index patients with group A  $\beta$ -hemolytic streptococcal infection and their household contacts with respect to the attack rate of streptococcal pharyngitis within the household.

**TECHNICAL APPROACH:** Families with a child with group A Strep Pharyngitis C (pharyngitis with a throat culture positive for group A  $\beta$ -hemolytic strep) are randomized into one of two groups. Family members have a throat culture taken at the onset, and then are followed over the ensuing 3 months or any secondary cases of group A strep pharyngitis. Group A families have all household members at the onset receive Penicillin while Group B contacts only receive antimicrodials if they are symptomatic with a positive throat culture. The attack rate of secondary cases of strep pharyngitis is then compared between the two groups.

**PROGRESS:** No. of Subjects Enrolled - To Date: Reporting Period:

Enrolling of subjects did not begin until 8 September 1987. Three families are currently enrolled in the study and with the onset of school card probably more strep pharyngitis, the principal investigator anticipates no difficulty enrolling subject.

Detail Summary Sheet

Prot No: 24H87	Status: Ongoing
TITLE: Insomniac Alcoholics: Evaluation of Tryptophan Therapy	
Principal Investigator: Richard Chung, MD	
Associate Investigators: James Hall, PhD; LTC Terry Schultz, MC; CPT Kevin J. Took, MC	
Department/Section: Psychiatry	
Key Words: insomniac alcoholics; tryptophan	
Funding: FY 86: NA	FY 87: NA
Periodic Review Date: Apr 87	
Gifts: L-tryptophan and placebo	Decision: Continue

OBJECTIVE: To investigate the effect of l-tryptophan on the complaints of sleep disturbances in recovering alcoholics who are undergoing alcohol rehabilitation in a structured 6-week inpatient program.

TECHNICAL APPROACH: This study utilizes a double-blind, placebo controlled, parallel groups design. The subjects will be patients enrolled in the VA/TRISARF program who complain of insomnia and who meet inclusion/exclusion criteria. Their sleep will be evaluated by morning sleep questionnaires that assess their sleep at night as well as daytime sleepiness. All participants will have polysomnography on three nights for the diagnosis of sleep disorders other than insomnia due to alcoholism and to give objective evidence for changes in sleep architecture.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

Due to Dr. Chung's resignation as Chief of TAMC VA Psychiatry, funding through the VA has been delayed, and we have been unable to proceed with the study. Negotiations continue with the VA to release funding. Dr. Chung is continuing to work at TAMC as a consultant, formal approval pending.

# Detail Summary Sheet

Prot No: 20H87	Status: Ongoing
TITLE: The Effect of Verapamil on Tardive Dyskinesia	
Principal Investigator: CPT Timothy J. Kowalski, D.O.	
Associate Investigators: Richard A. Markoff, M.D., Thomas F. Ditzler, Ph.D. Richard Fuller, D.O.	
Department/Section: Psychiatry	
Key Words: Verapamil, Tardive Dyskinesia	
Funding: FY 86: NA	FY 87: NA
Gifts: None	Periodic Review Date: Feb 87 Decision: Continue

OBJECTIVE: To determine the effectiveness of verapamil in relieving or significantly decreasing the abnormal involuntary movements of tardive dyskinesia (TD).

TECHNICAL APPROACH: Double blind, placebo controlled, cross over study.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

Present plan is to attempt to schedule project from May 88 to Aug 88. Knoll Pharmaceuticals have verbally approved supplying placebo and drug for the study. Dr. Richard Fuller, D.O. will participate in the study as an associate investigator.

### Detail Summary Sheet

Prot No: 32H83	Status: Ongoing
TITLE: Prospective Study of the Use of Urinary D-Lactate Levels in Evaluation of the Acute Abdomen	
Principal Investigator: COL Peter J. Barcia, MC	
Associate Investigators: CPT Dino Saracino, MC; CPT Robert Thomas, Jr., MC	
Department/Section: Surgery/General Surgery	
Key Words: urinary D-lactate; acute abdomen	
Funding: FY 86: \$1,300. FY 87:	Periodic Review Date: Feb 87
Gifts: None	Decision: Continue

OBJECTIVE: To determine the usefulness of urinary D-lactate levels in the evaluation of the acute abdomen.

TECHNICAL APPROACH: Patients evaluated for acute abdominal pain will have urinary D-lactate and creatinine specimens collected every 12 hours from the initial evaluation until four collections postoperatively or it is determined the patient does not have an acute abdomen. In addition, ten preoperatively to serve as controls.

PROGRESS: No. of Subjects Enrolled - To Date:                      Reporting Period: 1

This study is still pending. One recent patient with fatal mesenteric vascular occlusion had, as predicted, an extremely high value in the CIS lab.

### Detail Summary Sheet

Prot No: 15T85	Status: Ongoing
TITLE: Animal Models for Advanced Trauma-Life Support Provider and Instructor Courses	
Principal Investigator: MAJ Richard G. Kilfoyle, MC (formerly: LTC Charles P. Carroll, MC)	
Associate Investigators: COL Donald W.S. Yim, MC; MAJ Frank Rogers, MS; MAJ Albert McCullen, VC	
Department/Section: Surgery/General Surgery	
Key Words: advanced trauma life support	
Funding: FY 86: NA FY 87: NA	Periodic Review Date: Oct 87
Gifts: None	Decision: Continue

OBJECTIVE: To fulfill the requirement of ATLS Provider and Instructor courses, i.e., to teach physicians a standardized approach to trauma care in the early hours of trauma patient assessment and to teach life-saving skills using animal models.

TECHNICAL APPROACH: Goats or pigs are deeply anesthetized with sodium pentobarbital and prepared for surgery. Participants then perform cricothyroidotomy, peritoneal lavage, chest tube placement, pericardiocentesis, and venous cutdown procedures under the close supervision of certified instructors. Animals are euthanatized at the end of the surgery laboratory.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

New Principal Investigator is MAJ Richard G. Kilfoyle, MC and Associate Investigator is COL Donald W.S. Yim, MC. Project should continue.

### Detail Summary Sheet

Prot No: 38T85	Status: Terminated
TITLE: Surgical Training Laboratory Using Animal Models	
Principal Investigator: LTC Charles P. Carroll, MC	
Associate Investigators: COL Peter J. Barcia, MC; LTC Y-T Lee, MC; LTC David W. Olson, MC; LTC George Wilkinson, MC	
Department/Section: Surgery/General Surgery	
Key Words: surgical training	
Funding: FY 86: NA	FY 87: NA
Gifts: None	Periodic Review Date: Sep 87 Decision: Terminate

OBJECTIVE: To train TAMC residents and interns in surgical techniques.

TECHNICAL APPROACH: Pigs under satisfactory general anesthesia underwent one saphenous vein cutdown, insertion of chest tube, pericardiocentesis, thoracotomy, peritoneal lavage, tracheostomy, and other standard surgical procedures. Animals were euthanatized at the completion of the surgery lab.

PROGRESS: No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

This requirement can be discontinued.



Detail Summary Sheet

Prot No: 31H87

Status: Ongoing

TITLE: The Physiologic Response of Antidiuretic Hormone (ADH) and Human Atrial Natriuretic Factor (hANF) to Hypotonic Volume Expansion Secondary to Sorbitol Bladder Irrigation During Transurethral Prostatectomy (TURP)

Principal Investigator: CPT Paul M. Desmond, MC

Associate Investigators: MAJ L. Harrison Hassell, MC, LTC Gary Wikert, MC  
John R. Claybaugh, Ph.D.

Department/Section: Surgery/Urology Service

Key Words: antidiuretic hormone; human atrial natriuretic factor

Funding: FY 86: NA

FY 87: NA

Periodic Review Date: Jul 87

Gifts:

Decision: Continue

OBJECTIVE: To assess the effect of hypotonic volume expansion, secondary to absorbed sorbitol, during TURP on ADH, hANF, renin, aldosterone and fluid and electrolytes. Both uncomplicated TURP procedures and those associated with TUR syndrome (Transurethral Resection Syndrome) will be evaluated. To postulate the roles of ADH, hANF, renin and aldosterone in the pathophysiology of the TUR syndrome in order to: 1) predict which patients are susceptible 2) propose methods during TURP for the avoidance of the syndrome in susceptible patients and 3) provide greater understanding of the pathophysiology of the TUR syndrome so it can be appropriately treated when it occurs.

TECHNICAL APPROACH: Venipuncture; multiple blood samples, weights

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period:

New start.

Detail Summary Sheet

Prot No: 16A86	Status: Ongoing
TITLE: Use of EEA Autosuture Device for Abdominoperineal Pull-Through Procedure for Hirschsprung's Disease	
Principal Investigator: LTC Y. C. Huang, MC	
Associate Investigators:	
Department/Section: Surgery/General Surgery	
Key Words: Hirschsprung's disease	
Funding: FY 86: \$700 FY 87:	Periodic Review Date: Sep 87
Gifts: EEA-type autosutures	Decision: Continue

**OBJECTIVE:** To study the feasibility and functional result of using an EEA autosuture device to perform colonostomy during abdominoperineal pull-through operation for Hirschsprung's disease (Swenson's and Soave's procedure).

**TECHNICAL APPROACH:** Using an abdominoperineal approach, the distal descending colon will be anastomosed to the anus by means of an EEA autosuture device. A 10 cm segment of the distal colon will be resected to simulate the resection of unhealthy bowel in a person. The animal will be observed daily for three weeks for its ability to defecate and stool character. The animal will then be euthanized and the entire anastomosis area will be dissected longitudinally to examine the relation of neorectum to the sphincter muscle.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

All animals survived. Two showed stenosis on x-ray study. Dilatation was carried out under light anesthesia. All animals were sacrificed at six weeks.

Use of EEA type all to anastomotic instrument for Swenson's pull-through operation for Hirschsprung's disease is feasible, easy and uniform. Stenosis of anastomosis may require dilatation. Plan human application.

# Detail Summary Sheet

Prot No: 14T85	Status: Ongoing
TITLE: Microvascular Lab-Psychomotor Skills	
Principal Investigator: MAJ Thomas G. Fry, MC (formerly: MAJ Steven V. Moore, MC)	
Associate Investigators:	
Department/Section: Surgery/Orthopedics	
Key Words: training; psychomotor skills	
Funding: FY 86: \$300.	FY 87:
Gifts: None	Periodic Review Date: Sep 86 Decision: Continue

OBJECTIVE: To maintain competency in microvascular technique, including anastomosis of 1 mm rat arteries and veins.

TECHNICAL APPROACH: Rats are anesthetized with sodium pentobarbital and one femoral artery and/or vein is transected and then reanastomosed. The wound is observed daily for any complications.

PROGRESS: No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Expect to have 3-5 residents participate for 4-8 weeks each in 1988.

## Detail Summary Sheet

Prot No: 9H87	Status: Ongoing
TITLE: Gait Efficiency of AK Amputees; The Effects of Prosthetic Components	
Principal Investigator: CPT Richard A. Hynes, MC	
Associate Investigators: COL Michael Romash, MC; CPT Beau J. Freund, MSC	
Department/Section: Surgery/Orthopedic Service	
Key Words: AK Amputees; Prosthetic feet	
Funding: FY 86: NA	FY 87: Periodic Review Date: Apr 87
Gifts: Prosthetists' time	Decision: Continue

**OBJECTIVE:** (1) To determine if socket design and terminal devices, especially kinetically active terminal devices, change the efficiency of gait of above-knee (AK) amputees, and (2) to establish a scientific basis and experimental program upon which foot terminal devices can be compared using the energy expenditure of gait as a modality for comparison.

**TECHNICAL APPROACH:** Using treadmill to assess energy consumption.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period:

One subject. Prosthesis is now completed. Preliminary testing of this pilot case is to begin in next few weeks with myself and CPT Freund.

# Detail Summary Sheet

Prot No: 20H86	Status: Ongoing
TITLE: The Role of Intralesional Steroids in the Acute Care of Fractures of the Distal Radius	
Principal Investigator: CPT Richard A. Hynes	
Associate Investigators: MAJ Courtenay S. Whitman, IV	
Department/Section: Surgery/Orthopedic Service	
Key Words: fractures; intralesional steroids; hematoma	
Funding: FY 86: \$300.	FY 87: NA
Gifts: None	Periodic Review Date: Jan 87
	Decision: Continue

OBJECTIVE: To determine the efficacy of steroid injections into the hematoma of acute wrist fractures as a means of decreasing postinjury edema, pain, and stiffness. The study will also examine any effects on healing time.

TECHNICAL APPROACH: A prospective blind study will be undertaken to evaluate the clinical effects of intralesional steroid injections.

PROGRESS: No. of Subjects Enrolled - To Date: 15      Reporting Period: 15

The principal investigator has been away at Shriners for 4 months and project has not proceeded without him. The project is expected to start again upon the return of the principal investigator.

# Detail Summary Sheet

Prot No: 34H87	Status: Ongoing
TITLE: Otic Pruritis in Patients with Atopic Disease	
Principal Investigator: CPT Charles F. Kava, MC	
Associate Investigators: MAJ Robert E. Bowen, MC; MAJ Larry A. Zieske, MC	
Department/Section: Surgery/Otolaryngology Service	
Key Words: otic pruritis; atopic disease	
Funding: FY 86: NA	FY 87: NA
Gifts: None	Periodic Review Date: Jul 87
	Decision: Continue

OBJECTIVE: To determine what proportion of patients seen at TAMC who suffer from one or more of the "classic" manifestations of atopic disease (asthma, rhinitis and eczema) are troubled by pruritis in the ear canals. Next, to determine whether this symptom actually represents a manifestation of atopic disease versus an unrelated phenomenon (i.e. due to mechanical irritation or lack of cerumen).

TECHNICAL APPROACH: 2-arm study of Seldane and Duravent measured by symptom score sheets.

PROGRESS: No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

No report filed for FY87.

## Detail Summary Sheet

Prot No: 19H87

Status Ongoing

TITLE: Peritonsillar Abscess: Treatment with Needle Aspiration and Oral Antibiotics vs. Incision and Drainage and IV Antibiotics

Principal Investigator: MAJ Gregory A. Antoine, MC

Associate Investigators: MAJ Mark H. Raterink, MC; CPT Alfred O. Park, MC;  
CPT Michael P. Martin, MC; CPT Chip Kava, MC;  
CPT Richard D. Kopke, MC

Department/Section: Surgery/Otolaryngology Service

Key Words: Peritonsillar Abscess

Funding: FY 86: NA

FY 87: NA

Periodic Review Date: Apr 87

Gifts: None

Decision: Continue

OBJECTIVE: To establish an effective treatment regimen for peritonsillar abscess which can be utilized by non-otolaryngologists and paraprofessional personnel in a military field setting.

TECHNICAL APPROACH: The peritonsillar area is aspirated three times with a syringe and 18 gauge needle, if pus is found they are enrolled (offered enrollment) in the study.

PROGRESS: No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

Only one subject has been enrolled.

### Detail Summary Sheet

Prot No: 2T84	Status: Ongoing
TITLE: Training Protocol for Microsurgery	
Principal Investigator: MAJ Stuart B. Kincaid, MC	
Associate Investigators:	
Department/Section: Surgery/Plastic Surgery	
Key Words: training; microsurgery	
Funding: FY 86: 0	FY 87: NA
Gifts: None	Periodic Review Date: Sep 86
	Decision: Continue

OBJECTIVE: To develop and maintain proficiency in microvascular anastomosis of veins, arteries, and nerves.

TECHNICAL APPROACH: The groin vessels of the rat or rabbit will be transected and reanastomosed using microvascular principles. The ears of the rabbit will be transected near its junction with the scalp and replantation attempted through microvascular techniques.

PROGRESS: No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

One year ago, at this time, I agreed to keep my name on this project to allow students and residents to practice micro surgical techniques, but unless specifically requested, it was understood that I would not participate directly. I am willing to continue on the basis of any genuine interest on the part of surgical residents to pursue individual training in this technique. Otherwise, no funds are requested for 1988.



### Detail Summary Sheet

Prot No: 23H86	Status: Ongoing
TITLE: Comparison of Open Surgical and Transvenous Interruption of Varicocele in Infertile Males	
Principal Investigator: CPT Karl J. Kreder, MC	
Associate Investigators: COL Martin Dresner, MC; LTC William G. Kennon, MC; MAJ Jean Laberge, MC; CPT Marc Pliskin, MC; CPT Paul Desmond, MC	
Department/Section: Surgery/Urology Service	
Key Words: varicocele; male fertility	
Funding: FY 86: \$5,000. FY 87:	Periodic Review Date: Aug 87
Gifts: none	Decision: Continue

**OBJECTIVE:** This is a randomized, prospective, controlled, comparative trial of two standard approaches for the treatment of varicocele, presumed to cause infertility.

**TECHNICAL APPROACH:** One hundred patients with infertility and otherwise healthy, on no medication, with a varicocele, normal hormonal studies, and abnormal SPA (less than 10%) will undergo a prospective, randomized, and controlled study. Study participants will have SPA and semen analysis at 1, 3, and 6 months and will be randomized into two groups, one undergoing inguinal ligation and the other percutaneous transvenous embolization. Both groups will have follow-up SPA and semen analysis at 3, 6, 9, and 12 months. Data collected will be used to (a) determine the success rate of percutaneous and surgical repair of varicocele, (b) determine the failure rate of both methods, (c) determine the relationship of varicocele size to success rates, (d) determine the ability of the SPA to predict successful repair, (e) correlate semen analysis results with successful varicocele repair, and (f) determine whether grading of the size of varicocele by physical examination correlates with ultrasound.

**PROGRESS:** No. of Subjects Enrolled - To Date: 30      Reporting Period: 30

Results thus far have been disappointing. Approximately 30 patients have been evaluated for inclusion into this study. However, over 85% of those have terminated participation because of various reasons including:

1. early reassignment
2. Lack of interest
3. prolonged deployment, etc.

I feel this study is a valid one, but needs modification to shorten the time necessary to complete (currently 18 months) if it is to yield any meaningful result.

# Detail Summary Sheet

Prot No: 5A87	Status: Ongoing
TITLE: The Use of Treated Umbilical Vein Graft as a Tissue Substitute in the Urinary Tract of Pigs	
Principal Investigator: MAJ Karl J. Kreder, Jr., MC	
Associate Investigators: COL Martin Dresner, MC; LTC William Kennon, MC; COL Douglas Soderdahl, MC; CPT Mark Pitts, MC; MAJ Albert McCullen, VC	
Department/Section: Surgery/Urology Service	
Key Words: umbilical vein graft	
Funding: FY 86: NA	FY 87: Periodic Review Date: Nov 86
Gifts: none	Decision: Continue

**OBJECTIVE:** To determine if treated umbilical vein will survive when implanted in the urinary tract.

**TECHNICAL APPROACH:** Six pigs have been used for Implantation of umbilical vein. The Implant was done full thickness into the anterior bladder wall as described in the original protocol. All pigs survived until sacrifice approximately 10 weeks post operatively.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA Reporting Period: NA

Two pigs extruded the graft entirely and it was free in the bladder. Two pigs partially extruded the graft. Two pigs seemed to incorporate some graft material into the bladder wall although the dacron backing was extruded. Necropsy examination of the bladders showed marked inflammatory reaction.

We plan to implant 6 more pigs with the following modifications:

1. Do not use Dacron backing on the graft.
2. One half of the implants are to be submucosal.
3. Longer use of antibiotics.

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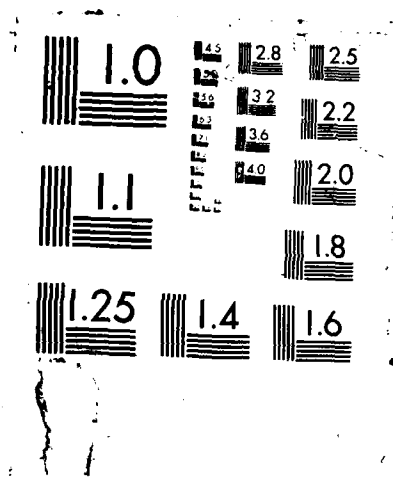
CLINICAL INVESTIGATION PROGRAM FISCAL YEAR 1987(U)  
TRIPLER ARMY MEDICAL CENTER HI DEPT OF CLINICAL  
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# Detail Summary Sheet

Prot No: 17E78	Status: Ongoing
TITLE: Human Implantation of Intraocular Lenses	
Principal Investigator: COL Anthony P. Martyak, MC	
Associate Investigators:	
Department/Section: Surgery/Ophthalmology	
Key Words: intraocular lenses	
Funding: FY 86: \$300. FY 87:	Periodic Review Date: May 87
Gifts: None	Decision: Continue

OBJECTIVE: To study the effects of implantation of intraocular lenses in humans.

TECHNICAL APPROACH: Utilization of posterior chamber intraocular lenses requires an extracapsular cataract method with preservation of the posterior lens capsule. Anterior chamber intraocular lenses are used after a routine intracapsular cataract extraction, as secondary implants, and when the posterior capsule is broken during an extracapsular cataract procedure.

PROGRESS: No. of Subjects Enrolled - To Date: Reporting Period: 99

During FY 87, 99 intraocular lenses were implanted in patients. 13 of the lenses were anterior chamber and 86 were posterior chamber lenses. Eighty-eight of the implants were primary implants (done at the time of original surgery), and 11 were secondary implants. There have been no adverse reactions from the lenses and none have required removal. The currently used posterior and anterior chamber lenses have been removed from investigational status by the FDA. No IRC is required for our currently used lenses. However, if we should stock any of the newer designed lenses which would be in the Adjunct Study phase and considered investigational by the FDA, an IRC would be necessary.

## Detail Summary Sheet

Prot No: 1H87	Status: Completed
TITLE: The Use of Intraurethral Cocaine Anesthesia in Male Outpatient Cystoscopy	
Principal Investigator: CPT Marc J. Pliskin, MC	
Associate Investigators: COL Martin Dresner, MC; COL William Kennon, MC; CPT Karl Kreder, MC; CPT Paul Desmond, MC; COL Douglas Soderdahl, MC	
Department/Section: Surgery/Urology	
Key Words: cystoscopy, cocaine anesthesia	
Funding: FY 86: NA	FY 87: Periodic Review Date: Nov 87
Gifts: none	Decision: Completed

**OBJECTIVE:** To demonstrate via a controlled randomized, double-blind, prospective study whether intraurethral cocaine anesthesia combined with lidocaine jelly provides greater patient comfort in male outpatient cystoscopy than lidocaine jelly alone.

**TECHNICAL APPROACH:** 5cc of 4% cocaine solution or and identical appearing placebo solution was instilled down the urethra of male patients undergoing cystoscopy followed by 15 ml of 2% lidocaine jelly. Cystoscopy was performed and the patient and physician then filled out questionnaire quantifying the degree of pain and tolerance to the procedure respectively. No adverse effects.

**PROGRESS:** No. of Subjects Enrolled - To Date: 80      Reporting Period: 80

The study has been completed. There was no (statistically) significant effect of combining cocaine with lidocaine in decreasing patient discomfort. This supports prior work in the pharmacologic literature on the human tongue using electric current which showed no summation effect in combining two local anesthetics. This study yielded some very valuable information though - lidocaine was effective alone, yielding pain from cystoscopy of 3 on a scale of 10. We also showed that older men tolerate cystoscopy better - statistically significant. We feel that the pain of cystoscopy can be further lessened with anesthetizing the posterior urethra more efficiently (via a catheter) and a protocol using lidocaine alone is currently under design. The study we completed will be presented at the Kimbrough Urology Conference Nov 87 and will be submitted to Urology for publication soon. It is the second double-blind, randomized prospective study of urethral local anesthetics.

Detail Summary Sheet

Prot No: 23A87

Status: Ongoing

TITLE: The Use of Treated Umbilical Vein Graft as a Catheterizable Conduit in the Urinary Tract of Pigs

Principal Investigator: CPT Marc J. Pliskin, MC

Associate Investigators: CPT Karl J. Kreder, MC; COL Martin Dresner, MC;  
COL William Kennon, MC; LTC Gary Wikert, MC;  
CPT Gary Cooper, MC; MAJ Albert McCullen, VC

Department/Section: Surgery/Urology Service

Key Words: umbilical vein

Funding: FY 86: NA

FY 87:

Periodic Review Date: Jun 87

Gifts:

Decision: Continue

**OBJECTIVE:** To determine if treated umbilical vein will provide continent catheterizable conduit in the urinary tract.

**TECHNICAL APPROACH:** Treated human umbilical vein graft was used to create a conduit (catheterizable and non-leaking) from the bladder of the pig to the skin. X-rays and subsequent catheterization of the graft would be performed to determine survivability and technical success.

**PROGRESS:** No. of Subjects Enrolled - To Date: 4      Reporting Period: 4

This procedure has been performed on 4 pigs thus far with initial successful results in all 4. Each of the conduits remains catheterizable (we are performing this twice a week) and did not leak (due to the way it was implanted in the bladder (non-refluxing). X-ray studies have shown intact conduits. We plan to continue catheterizing each pig twice weekly until they are 12 weeks post-op then they will be sacrificed for pathologic study of the graft. Since this has been successful in each pig we do not feel any further pigs are necessary. I would like to present the preliminary results of this work to the Western Section American Urologic Association Conference in San Francisco in late February 1988. It will be submitted to Journal of Urology eventually.

## Detail Summary Sheet

Prot No: 7H87	Status: Ongoing
TITLE: Post-therapy Hypocalcemia in the Treatment of Patients with Hyperthyroidism	
Principal Investigator: MAJ Mark Raterink, MC	
Associate Investigators: MAJ Craig Holland, MC; MAJ Kris Raines, MC; MAJ Harrison Hassell, MC; CPT Donald Moe, MC; CPT Joel Link, MC	
Department/Section: Surgery/Otolaryngology	
Key Words: hypocalcemia, hyperthyroidism	
Funding: FY 86: NA	FY 87: NA
Gifts: none	Periodic Review Date: Nov 87 Decision: Continue

**OBJECTIVE:** To sort out the clinical importance of the first four following mechanisms: (1) post-treatment parathyroid deficiency, (2) thyrotoxic renal magnesium wasting, (3) thyrotoxic osteodystrophy, (4) renal hypercalciuria, and (5) other mechanisms.

**TECHNICAL APPROACH:** Measurement of blood Free T<sub>4</sub>, T<sub>3</sub> RIA, TSH thyroid antibodies, Mg, Ca, PTH, Calcitonin and urinary routine chemistry plus Ca, PO<sub>4</sub>, hydroxyproline and cyclic-AMP will be compared with medication dosages.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA  
New start.



## Detail Summary Sheet

Prot No: 15A87	Status: Ongoing
TITLE: Menisci Energy-Absorbing Characteristics of Pig Hind Knee with Both Static and Dynamic Loads	
Principal Investigator: CPT Kenneth Reesor, MC	
Associate Investigators: COL Kent Reinker, MC; MAJ John Uribe, MC; Mr. W. Ichimura, Biomedical Engineering Technician	
Department/Section: Surgery/Orthopedic	
Key Words: meniscal injuries	
Funding: FY 86: NA	FY 87: NA
Periodic Review Date: Feb 87	Decision: Continue
Gifts: None	

**OBJECTIVE:** To establish the energy-absorbing characteristics of the pig knee and to determine if these characteristics are dependent on the percentage of meniscal intact.

**TECHNICAL APPROACH:** Instrumentation to apply impact loading to isolated pig knees (slaughterhouse donations) will be developed and measurements made of 1) transmitted pressures 2) compression displacements and 3) circumferential elongation or expansion of exercise.

**PROGRESS:** No. of Subjects Enrolled - To Date:                      Reporting Period:

No report filed for FY87.

## Detail Summary Sheet

Prot No: 46A85	Status: Ongoing
TITLE: Altered Consciousness Induced by Overdrainage of Cerebrospinal Fluid	
Principal Investigator: COL Bernard Robinson, MC, USAR	
Associate Investigators: John R. Claybaugh, Ph.D.; MAJ Jon Graham, MC	
Department/Section: Surgery/Neurosurgery	
Key Words: cerebrospinal fluid	
Funding: FY 86: \$600. FY 87:	Periodic Review Date: Sep 87
Costs: None	Decision: Continue

**OBJECTIVE:** To create an animal model in which coma can be induced by overdrainage of cerebrospinal fluid. Additionally, we hope to be able to demonstrate complete reversal of coma by replacing the volume of CSF removed. We hope to characterize any changes induced by the test maneuver (CSF drainage) in the parameters studied.

**TECHNICAL APPROACH:** Various parameters of vital functions are to be monitored during the investigation. These include electroencephalogram, blood pressure, electrocardiogram, and pulse rate. The test animal will require a craniectomy and insertion of a reservoir to be used for the actual access to the intrathecal compartment chosen for removal of CSF.

**PROGRESS:** No. of Subjects Enrolled - To Date: NA      Reporting Period: NA

Progress as of 4 September 1987: The project is ongoing and the principal and associate investigators are permanent residents of Hawaii. Other active duty associate investigators have been added: MAJ Lawrence Spetka and MAJ James Doty of TAMC Neurosurgery. Active animal research has been temporarily suspended until essential equipment is procured (evoked response monitoring system and ICP monitoring device capable of being used via the implanted CSF reservoir). A technical paper is being written regarding the current animal model with CSF reservoir implanted. This model can be used to test the effects of physiologic and pharmacologic variables on CSF without significant trauma or injury to the CNS and is ideal for chronic experiments.

## Detail Summary Sheet

Prot No: 36E83	Status: Ongoing
TITLE: The Effect of Continuous Passive Motion on Intra-articular Trauma with Continuous Passive Motion Device (CPMD)	
Principal Investigator: COL Michael M. Romash, MC	
Associate Investigators: CPT Harald J. Henningsen, MC	
Department/Section: Surgery/Orthopedic	
Key Words: intra-articular trauma	
Funding: FY 86: 0    FY 87:	Periodic Review Date: Jun 86
Gifts: None	Decision: Continue

**OBJECTIVE:** To assess the effect of continuous passive motion of joint function and rehabilitation after injury and/or repair of knee.

**TECHNICAL APPROACH:** Patients with intra-articular injuries of tibial plateau fractures, ruptured knee ligaments, reconstructed knee ligaments, patellar fractures, and dislocated patellae will be placed in the CPMD immediately after treatment. This will be done in a sequential fashion, alternating those so treated with those treated in the present fashion with early active motion or intermittent passive motion with no crossover. A total of 100 patients will be studied. The two groups will be compared regarding range of motion, need for narcotic medications, and bleeding, and will be followed for as long as possible for sequelae to their injury. If further surgery becomes indicated on the involved joint, inspection of cartilage will be accomplished. Rehabilitation parameters will also be measured, thigh girth, ability to weight-lift, and the range and timing of return to active duty or productive employment will be ascertained.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0    Reporting Period: 0

No report filed for FY87.

## Detail Summary Sheet

Prot No: 40A86	Status: Ongoing
TITLE: The Effect of Infusing Embolic Material into the Liver as an Adjunct to Liver Resection in the Pig	
Principal Investigator: CPT Council C. Rudolph, MC	
Associate Investigators: CPT Robert Thomas, MC; MAJ Jean Laberge, MC; LTC Y-T Lee, MC; CPT Everett Gale, MC	
Department/Section: Surgery/General	
Key Words: Liver resection, embolic material	
Funding: FY 86: NA	FY 87: Periodic Review Date: Dec 86
Gifts: none	Decision: Continue

**OBJECTIVE:** To determine the efficacy of intraoperatively infusing embolic agents into the hepatic circulation prior to liver resection.

**TECHNICAL APPROACH:** Under general anesthesia, the left hepatic branch of the portal vein is isolated and ligated. 2-3 units of Ivalon particles are infused via the isolateral vein into the liver. The hepatic artery on the left is ligated. The left lobe of the liver is resected via finger fracture techniques. Intraop and postop parameters are measured to gauge blood work and operative ease.

**PROGRESS:** No. of Subjects Enrolled - To Date: Reporting Period:

The first three pigs enrolled were sacrificed and used to gain early experience in anatomy and operative techniques. Of the five subsequent pigs, only two have lived beyond the first postop week; both were control pigs. Three of the subsequent pigs died; one from an apparent biliary injury, the second from massive gastroparesis and the third from vascular compromise of the remaining liver. Only the first two of these pigs were embolized. It is apparent that liver resection in the pig is quite a postoperative undertaking (as per Dr. Cucinell's predictions) and changes to the protocol requesting only a three-day postoperative course with euthanasia at that time will be submitted. With the experience thus far, the operation itself can safely be undertaken in under 2½ hours. The three-day postop period will allow adequate measurements of the postup course yet will not subject the pig to a difficult and prolonged postoperative period which we are not presently equipped to guide the pig through.

### Detail Summary Sheet

Prot No: 22H85	Status: Ongoing
TITLE: Flow Cytometry Network for Bladder Cancer	
Principal Investigator: COL Douglas W. Soderdahl, MC	
Associate Investigators:	
Department/Section: Surgery/Urology	
Key Words: bladder cancer; flow cytometry	
Funding: FY 86: \$300. FY 87:	Periodic Review Date: May 86
Gifts: *	Decision: Continue

**OBJECTIVE:** To develop a laboratory flow cytometric network to study urinary bladder cancer.

**TECHNICAL APPROACH:** The application of flow cytometry to the diagnosis of cancer is still being actively investigated, and the work of this project will include evaluations for sample preparation and cell dispersal, cell fixation, and different staining techniques, as well as the implications of degrees of aneuploidy. This latter would include studies to evaluate the role of various papilloma virus in bladder cancer, to establish flow cytometry as an effective screening method in following recurrent disease, and in correlating the degree of aneuploidy with histological grade and progress.

**PROGRESS:** No. of Subjects Enrolled - To Date: 154      Reporting Period: 142

Samples being held pending assignment of new investigators to do flow cytometry.

\*Flow cytometry to be done at the Cancer Research Center of Hawaii

## Detail Summary Sheet

Prot No: 50H85	Status: Ongoing
TITLE: Arthroscopic Evaluation of Acute Primary Shoulder Dislocations	
Principal Investigator: CPT J. David Pitcher, Jr., MC (formerly: MAJ John Uribe, MC)	
Associate Investigator: COL Michael M. Romash, MC	
Department/Section: Surgery/Orthopedics	
Key Words: shoulder dislocation; arthroscopy	
Funding: FY 86: \$2,000. FY 87:	Periodic Review Date: Sep 86
Gifts: None	Decision: Continue

**OBJECTIVE:** To evaluate arthroscopically the lesions associated with shoulder dislocations and correlate these lesions with prognostic indicators relative to recurrent dislocations.

**TECHNICAL APPROACH:** Patient referral requests will be sent to all outlying clinics requesting referral of all patients with initial shoulder dislocations documented by radiographs. Patients entered into the study will be admitted to TAMC Orthopedic Service and placed on the surgery schedule. Arthroscopy will be performed as soon as possible after the injury. Intra-articular pathology will be documented on operative findings data sheets and photographs of pathology will also be maintained in the data file for each patient. Postoperatively, patients will be placed in shoulder immobilizers for three weeks, followed by physical therapy with range of motion and shoulder bridle strengthening program for four weeks. Patients will then be progressed to full duty over a four-week period, and will be followed monthly in Sports Medicine Clinic for six months to one year, documenting clinical progress. Subsequent clinical progress and recurrent dislocation will be correlated with initial pathology documented by arthroscopy.

**PROGRESS:** No. of Subjects Enrolled - To Date: 47      Reporting Period: 47

1) The results have been presented at the following meetings:

The NA Arthroscopy Meeting in Atlanta, Feb 87.  
Sports Medicine Society Meeting in Orlando, Jul 87.

2) Plans are to present the results to date at the following meeting:

The Pan-Pacific Orthopaedic Meeting in Honolulu, Oct 87.

3) Other centers have begun similar studies and their results are being combined with TAMC's. These institutions are: West Point and Hughston Clinic.

4) There have been 47 patients involved in the study to date. One surgical stapling has failed and has undergone the standard repair for re-dislocation. The new principal investigator assigned is CPT J. David Pitcher, Jr, MC and the new associate investigator is COL Michael M. Romash, MC.

## Detail Summary Sheet

Prot No: 22A87	Status: Ongoing
TITLE: D-lactate Excretion In Rat Model Of Ischemic And Infarcted Bowel	
Principal Investigator: CPT David M. Watts, MC	
Associate Investigators: COL Peter J. Barcia, MC; CPT Robert S. Thomas, MC; CPT Randy Hammill, MC; MAJ Albert McCullen, VC	
Department/Section: Surgery/General Surgery	
Key Words: D-lactate ischemic and infarcted bowel	
Funding: FY 86: NA	FY 87: \$3,490.
Gifts: None	Periodic Review Date: NA Decision: Continue

OBJECTIVE: Establish whether d-lactate is excreted in increased amounts in intestinal ischemia and infarction. A rat model of intestinal ischemia/infarction will be used.

TECHNICAL APPROACH: D-lactate is a bacterial metabolite which could potentially serve as a marker for early intestinal ischemia. This hypothesis is being investigated by measuring serum d-lactate levels in four different groups of rats. One group of animals undergoes sham surgery only (midline abdominal incision and closure). The three experimental groups undergo either permanent total ligation of the superior mesenteric artery, temporary superior mesenteric artery occlusion or ligation of a branch of the superior mesenteric artery. Serial d-lactate levels are measured to determine if d-lactate rises in relation to the degree of intestinal ischemia/infarction.

ADVERSE EFFECTS: Technical difficulties have been encountered in the collection of blood specimens. Four rats have died without collection of any specimens. Two other rats had carotid internal cannulas successfully placed but only one specimen was collected from each before they died.

PROGRESS: No. of Subjects Enrolled - To Date: 6      Reporting Period: 6

Only six subjects have been entered in the study thus far and no experimental results have been obtained because of the above mentioned technical difficulties. Discussion is ongoing with other investigators in order to adjust experimental methods to further pursue this study.

### Detail Summary Sheet

Prot No: 19H83	Status: Ongoing
TITLE: Phase II Study of Human Interferons- $\alpha$ (HuIFN- $\alpha$ (Le)) in Patients with Nasopharyngeal Carcinoma (NPC) and Determination of the Effect of IFN on Epstein-Barr virus (EBV)-related Immunological Markers	
Principal Investigator: COL Donald W. S. Yim	
Associate Investigators: Nathaniel Ching, M.D.; Thomas Lou, M.D.; Kevin Loh, M.D.; Meredith Pang, M.D.; Clara Ching, M.D.; Thomas Merigan, M.D.	
Department/Section: Surgery/Otolaryngology	
Key Words: Interferon- $\alpha$ ; nasopharyngeal carcinoma	
Funding: FY 86: 0      FY 87: NA	Periodic Review Date: Jun 87
Gifts: Interferon	Decision: Continue

**OBJECTIVE:** (1) To determine the objective response rate to HuIFN- $\alpha$ (Le) in patients with NPC. (2) To measure time and onset and duration of response. (3) To determine changes in EBV-related immunologic markers in response to IFN. (4) To determine clinical and laboratory factors that correlate with therapeutic activity. (5) To determine the toxicity of IFN in patients with NPC.

**TECHNICAL APPROACH:** Approximately 20 patients will be enrolled in the study who have received at least two weeks of treatment with (HuIFN- $\alpha$ (Le)). Approximately 10 patients will be entered from Hawaii. This Honolulu aspect of the study will be in collaboration with Dr. Thomas Merigan who is the principal investigator at Stanford University, and the interferon will be administered under his IND number for use of the investigational drug.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 0

This is an on-going study. No new patients admitted to Tripler.



# Detail Summary Sheet

Prot No: 26D84	Status: Ongoing
TITLE: Use of Sodium Allopurinol to Control Hyperuricemia in Patients With No Therapeutic Alternative	
Principal Investigator: MAJ William C. Browning, MS (formerly: CPT Dominic A. Solimando, Jr., MS)	
Associate Investigators: COL Jeffrey L. Berenberg, MC; MAJ Bruce A. Cook, MC; MAJ William J. Uphouse, MC; MAJ Luke Stapleton, MC	
Department/Section: Pharmacy Service/Oncology	
Key Words: hyperuricemia; allopurinol	
Funding: FY 86: 0	FY 87: 0
Gifts: Allopurinol	Periodic Review Date: Sep 87 Decision: Continue

**OBJECTIVE:** To provide a water soluble form of allopurinol that can be given intravenously to patients with hyperuricemia who are too ill to take oral medication.

**TECHNICAL APPROACH:** This is a "convenience" protocol to make an uncommonly required dosage form available for use without the need for individual, special exception approval of the committee for each patient. This study also centralizes and simplifies the procedures for requesting the drug for patients. It is anticipated that 1-2 patients a year will be treated on this protocol.

**PROGRESS:** No. of Subjects Enrolled - To Date: 8      Reporting Period: 0

No additional patients were entered on the study between 1 Oct 86 and 30 Sep 87. A total of eight patients have been entered on the study. The study remains open.

### Detail Summary Sheet

Prot No: NSABP B13(84)	Status: Ongoing
TITLE: A Protocol to Assess Sequential Methotrexate-5-FU in Patients with Primary Breast Cancer and Negative Axillary Nodes Whose Tumors Are Negative for Estrogen Receptor	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: breast cancer	
Funding: FY 86: \$300. FY 87:	Periodic Review Date: Apr 87
Gifts: Fluorouracil and Leucovorin	Decision: Continue

OBJECTIVE: To determine if giving a relatively nontoxic chemotherapy program to women after surgery will decrease the chances of relapse and improve survival.

TECHNICAL APPROACH: All eligible patients are randomized to receive (1) chemotherapy with 5-FU and methotrexate twice a month for 1 year or (2) no treatment.

PROGRESS: No. of Subjects Enrolled - To Date: 4      Reporting Period: 0

A total of four Tripler patients have been registered on this protocol. The number of patients accrued nationally has been good; Hematologic toxicity has been mild. Gastrointestinal toxicity (nausea, vomiting, diarrhea, and stomatitis) has been noted, but has not been life-threatening. There are no available data on relapse.

### Detail Summary Sheet

Prot No: NSABP B14(84)	Status: Ongoing
TITLE: A Protocol to Assess Tamoxifen in Patients with Primary Breast Cancer and Negative Axillary Nodes Whose Tumors Are Positive for Estrogen Receptors	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: breast cancer	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Apr 87
Gifts: Tamoxifen/Placebo	Decision: Continue

**OBJECTIVE:** To determine if Tamoxifen given to women after surgery for breast cancer will prolong survival and prevent recurrences.

**TECHNICAL APPROACH:** All patients who are eligible are randomized to tamoxifen p.o. for 4 years or placebo p.o. for 4 years.

**PROGRESS:** No. of Subjects Enrolled - To Date: 8 Reporting Period: 1

Seven patients have been entered on this study from Tripler. Accrual of patients has been excellent nationally; over 1,000 eligible patients have been randomized. Toxicity reported has been mild gastrointestinal and menopausal symptoms. Treatment arms are coded and there are no obvious differences. No data are available on relapse.

### Detail Summary Sheet

Prot No: NSABP B15(84)	Status: Ongoing
TITLE: A Three-Arm Clinical Trial Comparing Short Intensive Chemotherapy With or Without Reinduction Chemotherapy to Conventional CMF in Receptor-Negative Positive-Node Breast Cancer Patients	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC; LTC Joseph Woods, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: breast cancer	
Funding: FY 86: \$300. FY 87:	Periodic Review Date: Apr 87
Gifts: Fluorouracil	Decision: Continue

**OBJECTIVE:** To determine if a short course of chemotherapy in the adjuvant setting is as effective as the "standard" six months of CMF. Also, to determine if a later "reinduction" will improve survival.

**TECHNICAL APPROACH:** Patients agreeing to participate will be randomized to one of three treatment groups: (1) Adriamycin and Cytosan for four cycles, (2) Adriamycin and Cytosan as above, then, after six months of rest, three cycles of CMF, or (3) six cycles of CMF ("standard" therapy).

**PROGRESS:** No. of Subjects Enrolled - To Date: 4      Reporting Period: 1

Four patients have been entered at Tripler. Nationally, a large number of patients have been entered. One patient developed an allergic reaction which is a known complication.

# Detail Summary Sheet

Prot No: NSABP B16(84)	Status: Ongoing
TITLE: A Three-Arm Clinical Trial Comparing Tamoxifen Alone Versus L-PAM, 5-FU, and Tamoxifen Versus Short Intensive Adriamycin-Cyclophosphamide Plus Tamoxifen in Receptor-Positive Node-Positive Breast Cancer Patients	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC; LTC Joseph Woods, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: breast cancer	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Jan 87
Gifts: Fluorouracil, Tamoxifen, Alkeran	Decision: Continue

**OBJECTIVE:** To determine if chemotherapy added to tamoxifen is superior to tamoxifen alone in the adjuvant therapy of receptor-positive breast cancer. Also, to determine which of two chemotherapy regimens, when added to tamoxifen, results in the best survival.

**TECHNICAL APPROACH:** Patients agreeing to participate in this study will be randomized to one of three treatments: (1) tamoxifen alone for four years, (2) tamoxifen for four years, plus four cycles of Adriamycin and Cytosan, or (3) tamoxifen for four years, plus L-PAM and 5-FU every six weeks for 17 courses.

**PROGRESS:** No. of Subjects Enrolled - To Date: 4      Reporting Period: 1

Four Tripler patients have been entered to date. It is too early for any analyses. No national data are available.

# Detail Summary Sheet

Prot No: NSABP B17(86)	Status: Ongoing
TITLE: A Clinical Trial to Evaluate Natural History and Treatment of Patients with Noninvasive Intraductal Adenocarcinoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC; LTC Lawrence Sakas; LTC Aida P. Ronquillo, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: adenocarcinoma, noninvasive intraductal	
Funding: FY 86: \$300.	FY 87: Periodic Review Date: Jan 87
Gifts: None	Decision: Continue

**OBJECTIVE:** To determine whether lumpectomy is an effective operation for the treatment of noninvasive breast cancer and if radiation treatments add to that effectiveness.

**TECHNICAL APPROACH:** Patients agreeing to participate in the study will be randomized after lumpectomy to receive or not receive radiation therapy to the involved breast.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study is open to TAMC patients at present.

### Detail Summary Sheet

Prot No: NSABP C02(84)	Status: Ongoing
TITLE: A Clinical Trial Evaluating the Postoperative Portal Vein Infusion of 5-FU and Heparin in Patients with Resectable Adenocarcinoma of the Colon	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse MC; COL Peter J. Barcia, MC; LTC Margaret Lee, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: colon adenocarcinoma	
Funding: FY 86: \$300. FY 87:	Periodic Review Date: Aug 87
Gifts: None	Decision: Continue

OBJECTIVE: To determine if 5-FU infused through the portal vein for one week postoperatively will decrease the recurrence rate of operable adenocarcinoma of the colon in comparison to a control group given no therapy.

TECHNICAL APPROACH: Patients who appear to have Dukes A, B, or C colon cancer and who agree to participate will be randomized preoperatively to receive a 5-FU and heparin infusion via the portal vein for 7 days postoperatively or to receive no further therapy.

PROGRESS: No. of Subjects Enrolled - To Date: 7      Reporting Period: 5

Seven Tripler patients have been entered to date. Nationally, several hundred patients were randomized. Preliminary toxicity analysis indicates no bone marrow or surgical toxicity. This study remains open.

### Detail Summary Sheet

Prot No: POG 8104(83)	Status: Ongoing
TITLE: Comprehensive Care of the Child with Neuroblastoma: A Stage and Age Oriented Study, Phase III	
Principal Investigator: MAJ Bruce A. Cook, MC (formerly: LTC Stephen R. Stephenson, MC)	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: neuroblastoma	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Aug 87
Gifts: VM-26	Decision: Continue

**OBJECTIVE:** Attempts to reduce later complications by separating by age and stage those patients that require surgery only, surgery and chemotherapy, surgery, chemotherapy, and radiation therapy, etc.

**TECHNICAL APPROACH:** Pediatric patients and adolescent patients under the age of 18 with neuroblastoma are eligible for enrollment in this study. Treatment will be as outlined in the study protocol.

**PROGRESS:** No. of Subjects Enrolled - To Date: 5      Reporting Period: 0

The last national data available in summary form is from last year. At that time the data was as follows: Nationally, 455 patients have been entered on this study; 345 patients are considered fully evaluable. Current Stage A less than 1 year shows a greater than 90% disease-free survival (DFS) at four years; Stage A greater than one year, 90% DFS at four years. Stage B greater than one year shows a four-year DFS of approximately 65%, while Stage B greater than one year shows a four-year DFS of 50%. Stage C patients greater than one year show a DFS at four years of approximately 52%. Stage C less than one-year show a DFS at 4 years of greater than 85%. Stage D patients' survival is still quite poor at approximately 10% at four years.



# Detail Summary Sheet

Prot No: POG 8158(83)	Status: Ongoing
TITLE: NWTs Long Term Follow-up Study	
Principal Investigator: MAJ Bruce A. Cook, MC (formerly: LTC Stephen R. Stephenson, MC)	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: Wilm's tumor	
Funding: FY 86: \$300.    FY 87: \$300.	Periodic Review Date: Aug 87
Gifts: None	Decision: Continue

**OBJECTIVE:** To examine the late consequences of successful treatment given for Wilms' tumor.

**TECHNICAL APPROACH:** Pediatric patients and adolescent patients under 18 years of age with Wilms' tumor will be eligible. Treatment will be as outlined in the study protocol.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No TAMC patients have been entered into this protocol as yet. This is a non therapeutic study designed to gather epidemiologic and late effects data on long term (>5yrs) survivors of Wilm's tumor. No Tripler patients have been registered to date. Nationally 140 patient registrants have been accrued. No detailed results are available yet and the study remains open.

# Detail Summary Sheet

Prot No: POG 8336(86)	Status: Terminated
TITLE: Evaluation of AZQ in Pediatric Patients with Recurrent Brain and Other Solid Tumors, Phase II	
Principal Investigator: MAJ Bruce Cook, MC (formerly: LTC Stephen R. Stephenson, MC)	
Associate Investigators: LTC Joseph Woods; COL Peter Barcia	
Department/Section: Pediatric/Hematology-Oncology Service	
Key Words: brain tumors, pediatric	
Funding: FY 86: \$300.	FY 87: \$300.
Gifts: AZQ	Periodic Review Date: Sep 87 Decision: Terminate

**OBJECTIVE:** To evaluate the use of AZQ in pediatric patients with recurrent brain and other solid tumors, phase II.

**TECHNICAL APPROACH:** AZQ is to be given as a four-hour IV infusion weekly for four weeks followed by a two-week rest. The dose is 13 mg/M<sup>2</sup>. The drug is to be continued until cure or documented disease progression.

**PROGRESS:** No. of Subjects Enrolled - To Date: 2      Reporting Period: 2

Much of the data is too early for evaluation. No abstracts/publications have yet been published. The study is now closed as enough patients have been registered to answer the research question.

# Detail Summary Sheet

Prot No: POG 8346(85)	Status: Ongoing
TITLE: Comprehensive Therapy for Ewing's Sarcoma: Tailored Versus Standard Radiation Therapy, Phase III	
Principal Investigator: MAJ Bruce A. Cook, MC; (formerly: LTC Stephen R. Stephenson, MC)	
Associate Investigators: LTC Joseph Woods, MC; LTC Aida Ronquillo, MC; COL Peter Barcia, MC	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: Ewing's sarcoma	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Aug 87
Gifts: None	Decision: Continue

**OBJECTIVE:** This study is directed toward comprehensive care of the child with Ewing's Sarcoma. Several questions are being asked in this study, but there are essentially two major points to the investigation: (1) Do sequential cyclophosphamide and Adriamycin produce complete or partial responses as well as group and historical controls? (2) Is local tumor control achieved as well with radiation therapy to a small field (tumor plus margin) as compared to the standard whole bone field?

**TECHNICAL APPROACH:** After initial induction chemotherapy, patients are evaluated to assess completeness of response. Patients are then randomized to small field or whole bone radiation.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

No TAMC patients have been registered on this protocol, it remains open to patient entry. One abstract has been accepted utilizing data from this study - SIOP - 1985.

### Detail Summary Sheet

Prot No: POG 8361(84)	Status: Ongoing
TITLE: VP 16-213 and 5-Azacytidine in Combination For Refractory Acute Nonlymphocytic Leukemia (ANLL), Phase II	
Principal Investigator: MAJ Bruce A. Cook, MC (formerly: LTC Stephen R. Stephenson, MC)	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: Leukemia, nonlymphocytic	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Aug 87
Gifts: VP-16	Decision: Continue

**OBJECTIVE:** Patients with ANLL under 21 years of age with disease refractory to standard drugs will be given a combination of nonstandard drugs shown to be effective in pilot studies. The objective is to improve response in these patients.

**TECHNICAL APPROACH:** This phase II study will test whether increasing the dose of VP-16 will produce hypoplasia in two versus three courses and improve response.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No TAMC patients have been registered. The study remains open. An abstract was published. AACR May 1985, pp. 22-25.

## Detail Summary Sheet

Prot No: POG 8426(86)	Status: Ongoing
TITLE: Intensive Chemotherapy (MOPP-ABVD) Plus Low-Dose Total Nodal Radiation Therapy in the Treatment of Stages IIB, III <sub>2</sub> A, IIIB, IV Hodgkin's Disease in Pediatric Patients, A Groupwide Pilot Study	
Principal Investigator: MAJ Bruce A. Cook, MC; (formerly: LTC Stephen R. Stephenson, MC)	
Associate Investigators: LTC Joseph Woods, MC; LTC Aida Ronquillo, MC	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: Hodgkin's disease	
Funding: FY 86: \$300.	FY 87: \$300.
Gifts: None	Periodic Review Date: Feb 87 Decision: Continue

**OBJECTIVE:** To determine if the addition of total nodal radiation therapy to standard chemotherapy will aid in disease-free survival and overall care.

**TECHNICAL APPROACH:** In this study, patients will receive alternating courses of MOPP-ABVD chemotherapy, with each course lasting 28 days. A cycle of therapy will consist of one course of MOPP and ABVD--thus a cycle equals 56 days. After 1½ cycles (3 months), clinical restaging will be performed (CT scans, chest x-ray, and possible biopsy). If the disease has not worsened, 1½ additional cycles will be given; then a second restaging will occur. Once again, as long as the disease has not worsened, the patient will receive an additional cycle of MOPP-ABVD. After a 6-week rest, a complete clinical restaging will be done, possibly including biopsy. If the patient is in complete remission, low-dose total nodal irradiation will be given. If, however, disease is present, no irradiation will be given and the patient will be off the study.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

One TAMC patient with Stage IV Hodgkin's Disease has been enrolled in this study. He completed therapy in March 1987. He is alive and well at this time.

### Detail Summary Sheet

Prot No: POG 8450(85)	Status: Terminated
TITLE: A Case-Control Study of Risk Factors for Wilm's Tumor, NWTs Intergroup Study with CCSG and POG	
Principal Investigator: MAJ Bruce A. Cook, MC (formerly: LTC Stephen R. Stephenson, MC)	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: Wilm's tumor	
Funding: FY 86: \$300. FY 87: NA	Periodic Review Date: Sep 87
Gifts: None	Decision: Terminate

**OBJECTIVE:** To study environmental exposures within hereditary and nonhereditary subgroups of Wilm's tumor to better understand the role that genetic-environmental factors play in the development of Wilm's tumor.

**TECHNICAL APPROACH:** All patients entered in the National Wilm's Tumor Study (NWTs) protocol are eligible. Data will be collected with a self-administered questionnaire and this data will be correlated with biologic data from the NWTs forms.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This is a non therapeutic protocol. No TAMC patients have been enrolled.

# Detail Summary Sheet

Prot No: POG 8451(86)	Status: Ongoing
TITLE: Intergroup Rhabdomyosarcoma - Study III	
Principal Investigator: MAJ Bruce A. Cook, MC (formerly: LTC Stephen R. Stephenson, MC)	
Associate Investigators:	
Department/Section: Pediatric/Hematology-Oncology	
Key Words: rhabdomyosarcoma	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Oct 87
Gifts: Drugs	Decision: Continue

OBJECTIVE: This protocol is the new Intergroup Rhabdomyosarcoma III study designed to provide definitive care to all new cases of rhabdomyosarcoma less than 21 years of age.

TECHNICAL APPROACH: Multiagent chemotherapy and radiotherapy tailored to: site of disease, histologic subtype and stage of disease. Results will be compared to IRS I & II (historical controls).

PROGRESS: No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

One Tripler patient has been enrolled in this study. The patient is six months into therapy and has done very well with minimal toxicity.

### Detail Summary Sheet

Prot No: POG 8462(85)	Status: Terminated
TITLE: ICRF-187 in Children with Solid Tumors or Acute Leukemia, Phase II	
Principal Investigator: MAJ Bruce A. Cook, MC (formerly: LTC Stephen R. Stephenson, MC)	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: solid tumors; leukemia, acute	
Funding: FY 86: \$300. FY 87:	Periodic Review Date: Sep 87
Gifts: ICRF-187	Decision: Terminate

OBJECTIVE: To determine (1) the therapeutic efficacy of ICRF-187 in the treatment of children with leukemia or solid tumors and (2) the qualitative and quantitative toxicity to children given the drug daily for three days every three weeks.

TECHNICAL APPROACH: All patients agreeing to participate in the study will be treated with the same regimen.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This protocol is now closed. No TAMC patients were entered on this study.



Detail Summary Sheet

Prot No: POG 8464(85)	Status: Terminated
TITLE: Phase II Study of Carboplatin in the Therapy of Children with Progressive or Recurrent Brain Tumors	
Principal Investigator: MAJ Bruce A. Cook, MC (formerly: LTC Stephen R. Stephenson, MC)	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: brain tumor	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Sep 87
Gifts: Carboplatin	Decision: Terminate

OBJECTIVE: To determine the effectiveness of carboplatin in the treatment of children with brain tumors unresponsive to standard therapy, and to further evaluate the toxicities of the drug.

TECHNICAL APPROACH: All patients agreeing to participate in the study will receive (1) audiogram prior to each course of chemotherapy (if the patient is over 3 years of age and cooperative), and (2) Carboplatin to be given IV over one hour, preceded and followed by one hour of intravenous hydration.

PROGRESS: No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

One TAMC patient was entered on this study. He experienced only minimal toxicity (hematopoietic). Renal and auditory toxicity were closely looked at but did not develop. This patient was removed from study at the suggestion of the coordinator who felt the patient had received maximum benefit. This study is now closed.

### Detail Summary Sheet

Prot No: POG 8493(85)	Status: Ongoing
TITLE: Infant Leukemia Protocol, Group-Wide Pilot	
Principal Investigator: MAJ Bruce A. Cook, MC (formerly: LTC Stephen R. Stephenson, MC)	
Associate Investigators: LTC Joseph C. Woods, MC	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: infant leukemia	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Sep 87
Gifts: VM-26	Decision: Continue

OBJECTIVE: To study biologic differences of acute lymphocytic leukemia (ALL) in infants and improve the very poor disease-free survival in this group. A major objective is to identify toxicities and determine criteria for dose modification in infants.

TECHNICAL APPROACH: All patients will be treated with the same regimen and response rates will be compared to 75 controls from POG's previous ALL studies.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No TAMC patients have been enrolled in this study, which remains open at this time.

Detail Summary Sheet

Prot No: POG 8498(87)	Status: Ongoing
TITLE: Treatment of Children with Newly Diagnosed Acute Non-Lymphocytic Leukemia (ANLL) Using High-Dose Cytosine Arabinoside and Etoposide Plus 5-Azacytidine for Intensification of Early Therapy	
Principal Investigator: MAJ Bruce A. Cook, MC (formerly: LTC Stephen R. Stephenson, MC)	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: Acute Non-Lymphocytic Leukemia (ANLL); 5-Azacytidine	
Funding: FY 86:	FY 87: Periodic Review Date: Apr 87
Gifts: VP-16; 5-Azacytidine; Ara-C; Cytosan; 6-Thioguanine; Daunomycin	
Decision: Continue	

**OBJECTIVE:** (a) To explore the efficacy and feasibility of utilizing sequential courses of high-dose cytosine arabinoside (Hd A) and etoposide (VP) plus 5 azacytidine (AZ) for intensification of early therapy immediately following standard remission induction with daunomycin, ARA-C, and 6-thioguanine (DAT) in children with ANLL. (b) To determine the immediate and delayed toxicity of the above intensification method.

**TECHNICAL APPROACH:** The addition of an early intensification using sequential courses of drugs shown to be effective in resistant ANLL to the current most effective treatment regimen for childhood ANLL.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

One TAMC patient has been enrolled on this study. Toxicity has been limited to expected myelosuppression and mild nausea and vomiting. The patient is currently in remission and doing well.

### Detail Summary Sheet

Prot No: POG 8552(85)	Status: Ongoing
TITLE: A Case Control Study of Childhood Rhabdomyosarcoma	
Principal Investigator: MAJ Bruce A. Cook, MC (formerly: LTC Stephen R. Stephenson, MC)	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: rhabdomyosarcoma	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Sep 87
Gifts: None	Decision: Continue

OBJECTIVE: To evaluate the relationships between environmental exposures, gestational factors, and genetic factors in childhood rhabdomyosarcoma.

TECHNICAL APPROACH: Data will be collected by telephone interview conducted by the Intergroup Rhabdomyosarcoma Group and by a questionnaire. These data will be correlated with biologic data collected from treatment protocol forms.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No TAMC patients have been enrolled on this study to date. It remains open.

### Detail Summary Sheet

Prot No: POG 8600/01/02 (86)	Status: Ongoing
TITLE: Laboratory Classification in Acute Lymphoid Leukemia of Childhood (ALinC 14C), Phase III	
Principal Investigator: MAJ Bruce A. Cook, MC (formerly: LTC Stephen R. Stephenson, MC)	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: leukemia	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Feb 87
Gifts: None	Decision: Continue

OBJECTIVE: To thoroughly classify by laboratory methods the type of leukemia in children newly diagnosed with ALL, to see if better characterization of newly diagnosed leukemia can better define different prognostic groups. To provide comprehensive care of children newly diagnosed with ALL.

TECHNICAL APPROACH: Multiagent chemotherapy of ALL. Results of therapy will be compared to previous POG protocols for therapy of ALL which serve as historical controls. Data will be used to construct new treatment regimens based on prognostic groups and previous therapeutic studies.

PROGRESS: No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

One Pediatric patient enrolled at this time. No side effects from this classification have been noted.

Detail Summary Sheet

Prot No: POG 8631 (87)	Status: Ongoing
TITLE: Medulloblastoma Favorable Prognosis: Randomized Study of Reduced Dose Irradiation to Brain and Spinal Contents vs. Standard Dose Irradiation	
Principal Investigator: MAJ Bruce A. Cook, MC (formerly: LTC Stephen R. Stephenson, MC)	
Associate Investigators:	
Department/Section: Pediatrics/Hematology/Oncology	
Key Words: medulloblastoma; radiation	
Funding: FY 86: \$300. FY 87: NA	Periodic Review Date: Feb 87
Gifts: None	Decision: Continue

OBJECTIVE: To see if reduced irradiation to the spinal contents and supratentorial area of the brain can achieve an equal rate of disease-free survival and a lesser degree of psychomotor retardation as compared to standard dose irradiation.

TECHNICAL APPROACH: All registered children will be randomized into one of two treatment arms (a) Arm 1--3600 rads to whole brain and spinal contents plus an additional 1800 rads to posterior fossa, and (b) Arm 2--2340 rads to whole brain and spinal contents plus an additional 3060 rads to posterior fossa.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No Tripler patients have been enrolled in this study.

# Detail Summary Sheet

Prot No: POG 8651(86)	Status: Ongoing
TITLE: Osteosarcoma Study #2: A Randomized Trial of Pre-Surgical Chemotherapy vs Immediate Surgery and Adjuvant Chemotherapy in the Treatment of Nonmetastatic Osteosarcoma, Phase III	
Principal Investigator: MAJ Bruce A. Cook, MC (formerly: LTC Stephen R. Stephenson, MC)	
Associate Investigators:	
Department/Section: Pediatric/Hematology-Oncology	
Key Words: osteosarcoma, chemotherapy	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Dec 86
Gifts: Methotrexate	Decision: Continue

**OBJECTIVE:** To compare delayed surgery group to their immediate surgery controls to see if (1) those patients considered ineligible for limb salvage can be converted to candidates for limb salvage, and (2) preoperative chemotherapy improves disease-free survival.

**TECHNICAL APPROACH:** Multiagent chemotherapy utilizing methotrexate, adriamycin, cis-platinum, Bleomycin, Actinomycin-D and Cytosan over 42 weeks. One half of patients are randomized to immediate therapy. The remainder receive 10 weeks of adjuvant chemotherapy prior to definitive surgery.

**PROGRESS:** No. of Subjects Enrolled - To Date: 3      Reporting Period: 3

3 TAMC patients have been enrolled in this study. Toxicity has been primarily hematopoietic. Bleomycin induced (transient) pulmonary toxicity was noted in one patient. All patients are alive and well with no evidence of active disease.

### Detail Summary Sheet

Prot No: POG 8741/42(87)	Status: Ongoing
TITLE: Treatment of Stage D Neuroblastoma in Children Greater Than or Greater to 365 Days at Diagnosis	
Principal Investigator: MAJ Bruce A. Cook, MC (formerly: LTC Stephen R. Stephenson, MC)	
Associate Investigators:	
Department/Section: Pediatrics/Hematology-Oncology	
Key Words: neuroblastoma;	
Funding: FY 86: NA	FY 87: \$300.
Gifts: NA	Periodic Review Date: Jul 87 Decision: Continue

**OBJECTIVE:** This study is designed to look specifically at children in the worst prognostic groups of neuroblastoma. This study will employ four phase two agents in addition to standard chemotherapy.

**TECHNICAL APPROACH:** Children will be randomized to receive one of 4 phase two agents as initial drug therapy. After two courses they will then be randomized to one of two standard treatment arms for completion of therapy. Results will be compared to historical group controls.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

Newly activated. No patients registered at this time.



## Detail Summary Sheet

Prot No: SWOG 7804

Status: Ongoing

TITLE: Adjuvant Chemotherapy with 5-FU, Adriamycin and Mitomycin C (FAM) versus Surgery Alone for Patients with Locally Advanced Gastric Adenocarcinoma, Phase III

Principal Investigator: COL Jeffrey Berenberg, MC

Associate Investigators: MAJ William Uphouse, MC; COL Peter J. Barcia, MC

Department/Section: Medicine/Hematology-Oncology

Key Words: gastric adenocarcinoma

Funding: FY 86: \$300. FY 87: \$300.

Periodic Review Date: Jul 87

Gifts: None

Decision: Continue

OBJECTIVE: To determine whether or not chemotherapy (FAM) given to patients with advanced but resected gastric carcinoma will prevent relapses and prolong life.

TECHNICAL APPROACH: Patients will be randomized to either (1) receive chemotherapy with FAM twice a month for 1 year for (2) receive no treatment.

PROGRESS: No. of Subjects Enrolled - To Date: 1      Reporting Period: 0

There is only one TAMC patient on this study. It remains open with acceptable toxicity.

### Detail Summary Sheet

Prot No: SWOG 7808(83)	Status: Ongoing
TITLE: Combined Modality Treatment for Stage III and IV Hodgkin's Disease - MOPP 6, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC; MAJ Marylin P. Ordonez, MC; MAJ Aida Ronquillo, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: Hodgkin's disease	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Apr 87
Gifts: None	Decision: Continue

**OBJECTIVE:** To determine if radiation therapy given after the chemotherapy will increase the chance of being cured, and to see if a drug called levamisole given as a pill will increase the chance of being cured.

**TECHNICAL APPROACH:** As outlined in study protocol.

**PROGRESS:** No. of Subjects Enrolled - To Date: 13      Reporting Period: 13

National accrual is over 600. A total of 13 TAMC patients are in this study.

### Detail Summary Sheet

Prot No: SWOG 8049(84)	Status: Completed
TITLE: The Treatment of Resected Poor Prognosis Malignant Melanoma Stage I: Surgical Excision Versus Surgical Excision + Vitamin A, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: melanoma, malignant	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Jul 87
Gifts: None	Decision: Completed

OBJECTIVE: To determine if vitamin A given daily by mouth will decrease the relapse rate and improve survival in patients who have had poor prognosis melanomas completely resected.

TECHNICAL APPROACH: Patients with melanomas that extend deeper than .76 mm and that have been completely resected are randomized to receive vitamin A daily by mouth for 18 months or to receive no therapy.

PROGRESS: No. of Subjects Enrolled - To Date: 8      Reporting Period: 0

A total of 260 patients have been entered on this study. TAMC has registered no patients this year and has a total of eight patients on the study. There has been no serious toxicity reported. Interim results are no longer provided for open studies.

This study has just been completed as it has accrued its targeted number of patients.

Detail Summary Sheet

Prot No: SWOG 8104(83)	Status: Terminated
TITLE: Treatment of Advanced Seminoma (Stage CII(N <sub>4</sub> ) + CIII) with Combined Chemotherapy and Radiation Therapy, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC; MAJ Marylin Ordonez; MAJ Aida Ronquillo, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: seminoma	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Apr 87
Gifts: None	Decision: Terminate

OBJECTIVE: To determine if combined chemotherapy and radiation therapy is more effective in treatment of advanced seminoma than radiation therapy alone.

TECHNICAL APPROACH: As outlined in study protocol.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No new TAMC patients have been admitted to the study this year. No interim results were provided at the last group meeting. This study was recently terminated due to poor patient accrual.

Detail Summary Sheet

Prot No: SWOG 8107(84)	Status: Ongoing
TITLE: Management of Disseminated Melanoma Master Protocol	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: melanoma, disseminated	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Jul 87
Gifts: None	Decision: Continue

OBJECTIVE: To determine the relative activity of three chemotherapy programs in patients with metastatic melanoma: (1) DTIC and Actinomycin-D (2) Cis-platinum, and (3) Cis-platinum, Velban, and Bleomycin. In addition, to determine if prophylactic cranial irradiation will prevent the later development of brain metastases.

TECHNICAL APPROACH: Patients with metastatic melanoma are randomized to receive or not to receive 5 days of prophylactic cranial radiation. They are also randomized to receive one of the three chemotherapy programs listed above.

PROGRESS: No. of Subjects Enrolled - To Date: 6      Reporting Period: 6

Six patients from Tripler have been entered. No new TAMC patients have been entered this year. The phase II portion of this study was closed October 1984. The phase III portion of the study remains open to accrual.

### Detail Summary Sheet

Prot No: SWOG 8228(85)	Status: Completed
TITLE: Correlation Between Progesterone Receptor and Response to Breast Cancer, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC; MAJ Daniel T. Tell, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: breast cancer	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Jan 87
Gifts: None	Decision: Completed

OBJECTIVE: To determine if progesterone receptor level correlates with response of breast cancer to tamoxifen treatment.

TECHNICAL APPROACH: All patients agreeing to this study will receive p.o. tamoxifen until their cancer progresses.

PROGRESS: No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

Only one TAMC patient has been registered on this study. There are a large number of patients registered nationally. There has been no unanticipated toxicity and the study has been closed recently due to its reaching its targeted patient accrual goal.

# Detail Summary Sheet

Prot No: SWOG 8300(84)	Status: Ongoing
TITLE: Treatment of Limited Non-small Cell Lung Cancer: Radiation Versus Radiation Plus Chemotherapy (FOMi/CAP), Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC; MAJ Daniel Tell, MC; LTC Joseph Woods, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: lung cancer, non-small cell	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Apr 87
Gifts: None	Decision: Continue

**OBJECTIVE:** To determine whether chemotherapy added on to standard radiation therapy in patients with limited, non-small cell lung cancer will improve response rates and survival.

**TECHNICAL APPROACH:** Patients agreeing to participate in this study will be randomized to receive (1) definitive radiation therapy alone, or (2) 8 weeks of FOMi/CAP followed by definitive radiation and then two further cycles of FOMi/CAP. All patients are also randomized to receive or not receive prophylactic cranial irradiation.

**PROGRESS:** No. of Subjects Enrolled - To Date: 2      Reporting Period: 2

Two Tripler patient were registered on this protocol. Accrual has been good and no unusual or unanticipated toxicity has occurred.

Detail Summary Sheet

Prot No: SWOG 8312(85)	Status: Ongoing
TITLE: Megestrol Acetate and Aminoglutethimide/Hydrocortisone in Sequence or in Combination as Second-Line Endocrine Therapy of Metastatic Breast Cancer, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC; MAJ Daniel T. Tell, MC; LTC Joseph Woods, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: breast cancer, metastatic	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Jan 87
Gifts: None	Decision: Continue

**OBJECTIVE:** To determine if combined hormone therapies are superior to single hormone therapy in sequence for metastatic breast cancer.

**TECHNICAL APPROACH:** All patients agreeing to this study will be randomized to one of three treatments: (1) megestrol acetate, (2) aminoglutethimide plus hydrocortisone, or (3) megestrol acetate plus aminoglutethimide plus hydrocortisone.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

There are no TAMC patients on this study. Study remains open with no unanticipated toxicity. Accrual is adequate.



## Detail Summary Sheet

Prot No: SWOG 8324(87)	Status: Ongoing
TITLE: Evaluation of Fludarabine Phosphate in Malignant Melanoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: fludarabine phosphate; metastatic melanoma	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Apr 87
Gifts: None	Decision: Continue

**OBJECTIVE:** To determine the response rate and response duration in patients with malignant melanoma treated with fludarabine phosphate.

**TECHNICAL APPROACH:** Patients agreeing to participate will receive fludarabine IV push daily for 5 days every 4 weeks until relapse.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study remains open for patient accrual.

# Detail Summary Sheet

Prot No: SWOG 8326/27(85)	Status: Ongoing
TITLE: Evaluation of Combination Chemotherapy Using High Dose Ara-C in Adult Acute Leukemia and Chronic Granulocytic Leukemia in Blast Crisis, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC; MAJ Luke M. Stapleton, MC; MAJ Lawrence Sakas, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: Leukemia, adult acute; Leukemia, chronic granulocytic	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Jul 87
Gifts: None	Decision: Continue

**OBJECTIVE:** To determine the response and response duration of a high-dose program of Ara-C in patients with relapsed acute leukemia.

**TECHNICAL APPROACH:** Patients agreeing to the study will be randomized to receive (1) six days of high dose Ara-C, (2) the same Ara-C plus three days of m-AMSA, or (3) the same Ara-C plus three days of Mitoxantrone.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

There are no TAMC patients on this study. A number of patients have been entered nationally, and accrual continues.

Detail Summary Sheet

Prot No: SWOG 8369(85)	Status: Terminated
TITLE: Combination Chemotherapy with Mitoxantrone, Cis-Platinum, and MGBG for Refractory Lymphomas, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC; MAJ Daniel T. Tell, MC; MAJ Lawrence Sakas, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: Lymphoma	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Jul 87
Gifts: None	Decision: Terminate

OBJECTIVE: To determine the response role of refractory (previously treated) non-Hodgkin's lymphoma to a new combination of chemotherapy drugs.

TECHNICAL APPROACH: All patients agreeing to the study will receive the three drugs IV on day 1 and then every three weeks until disease progression occurs.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

There are no TAMC patients on this study. Nationally, there are a number patients on the study with one complete response. The study has been terminated recently. The program did some activity in lymphomas but not enough to warrant further study.

### Detail Summary Sheet

Prot No: SWOG 8390(84)	Status: Ongoing
TITLE: Chemotherapy of Gastric Cancer with 5-FU and Folinic Acid, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: gastric cancer	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Aug 87
Gifts: Folinic acid	Decision: Continue

**OBJECTIVE:** To determine the response rate of metastatic gastric carcinoma to a new combination of drugs (5-FU and folinic acid).

**TECHNICAL APPROACH:** Patients who agree to participate will be randomized to receive 5-FU either by constant IV infusion on day 1 through day 4, or by IV bolus on day 1 through day 5. Folinic acid will be given in both arms by IV bolus on each day of 5-FU. Courses will be repeated monthly.

**PROGRESS:** No. of Subjects Enrolled - To Date: 5      Reporting Period: 2

There are five TAMC patients on this study. Toxicity has been acceptable and this study will remain open. No response or survival data has been reported. Definite responses are being seen with this program.

# Detail Summary Sheet

Prot No: SWOG 8393(84)	Status: Ongoing
TITLE: National Intergroup Protocol for Intermediate Thickness Melanoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC; COL Peter J. Barcia, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: melanoma	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Aug 87
Gifts: None	Decision: Continue

OBJECTIVE: (1) To determine the optimal surgical margins (2 versus 4 cm) around the intermediate thickness melanomas (1-4 mm) that are being resected for cure. (2) To evaluate the value of elective regional lymph node dissection in these same melanomas.

TECHNICAL APPROACH: Patients with primary melanomas of the head or neck or distal extremities will be randomized to receive or not receive elective node dissection, but all patients in this group will have 2 cm surgical margins. Patients with melanomas of the trunk or proximal extremities will undergo two randomizations, (1) to receive or not to receive elective node dissection, and (2) to have either a 2 or 4 cm surgical margin.

PROGRESS: No. of Subjects Enrolled - To Date: 2      Reporting Period: 1

Two Tripler patients have been registered on this protocol. It is too early to assess efficacy of this protocol approach.

### Detail Summary Sheet

• Prot No: SWOG 8406(87) Status: Ongoing

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TITLE: Evaluation of Esorubicin in Malignant Lymphoma, Phase III

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Principal Investigator: COL Jeffrey Berenberg, MC  
Associate Investigators: MAJ William J. Uphouse, MC

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Department/Section: Medicine/Hematology-Oncology

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Key Words: esorubicin; malignant lymphoma

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Funding: FY 86: \$300. FY 87: \$300. Periodic Review Date: Apr 87  
Gifts: None Decision: Continue

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OBJECTIVE: To determine the response rate and response duration of malignant lymphoma treated with esorubicin.

TECHNICAL APPROACH: Patients agreeing to the study will receive esorubicin IV over five minutes every three weeks until progression of their tumor.

PROGRESS: No. of Subjects Enrolled - To Date: 1 Reporting Period: 0

This protocol remains open nationally as the drug is showing activity in some of the patients treated.

Detail Summary Sheet

Prot No: SWOG 8417/19(85)	Status: Ongoing
TITLE: Evaluation of the Consolidation Regimens in the Treatment of Adult Acute Lymphoblastic Leukemia, Phase III	
Principal Investigator: COL Jeffrey L. Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC; MAJ Daniel T. Tell, MC; MAJ Lawrence Sakas, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: leukemia, lymphoblastic	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Sep 87
Gifts: None	Decision: Continue

**OBJECTIVE:** To compare two consolidation chemotherapy programs in terms of remission, duration, and survival.

**TECHNICAL APPROACH:** All patients agreeing to participate will be randomized to receive either the L-10M consolidation or the new (shorter) consolidation program.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

No TAMC patients have been entered into this study to date. This study is the frontline study for patients with newly diagnosed acute lymphoblastic lymphoma and remains open.

Detail Summary Sheet

Prot No: SWOG 8465(87) Status: Completed

TITLE: High Dose Cisplatin in the Treatment of Metastatic Soft Tissue Sarcoma

Principal Investigator: COL Jeffrey Berenberg, MC

Associate Investigators: MAJ William J. Uphouse, MC

Department/Section: Medicine/Hematology-Oncology

Key Words: Cisplatin Metastatic soft tissue sarcoma

Funding: FY 86: \$300. FY 87: \$300. Periodic Review Date: Feb 87

Gifts: None Decision: Completed

OBJECTIVE: To determine the efficacy and toxicity of high-dose cisplatin in the treatment of metastatic soft tissue sarcomas.

TECHNICAL APPROACH: All patients agreeing to the study were to receive cisplatin monthly.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This study was recently closed as it has met its accrual goal.



Detail Summary Sheet

Prot No: SWOG 8493(85)	Status: Completed
TITLE: Simultaneous Cisplatinum Plus Radiation Therapy Compared with Standard Radiation Therapy in the Treatment of Unresectable Squamous or Undifferentiated Carcinoma of the Head and Neck	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC; MAJ Daniel Tell, MC; LTC Marilyn Ordonez, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: carcinoma, head and neck	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Jan 87
Gifts: None	Decision: Completed

**OBJECTIVE:** To determine if cisplatinum given simultaneously with radiation will improve the results of radiation alone in patients with unresectable head and neck cancer.

**TECHNICAL APPROACH:** All patients agreeing to this study will be randomized to receive either (1) radiation therapy alone or (2) radiation plus simultaneous weekly cisplatinum during the radiation only.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

There are no TAMC patients on this study. Accrual was good and no response data has been reported. This study has just closed to patient entry. Accrual was extremely rapid nationally and the study reached its targeted patient number in a very short period of time.

# Detail Summary Sheet

Prot No: SWOG 8504(86)	Status: Completed
TITLE: Evaluation of Menogaril in Renal Cell Carcinoma, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse; MAJ Daniel T. Tell; LTC Lawrence Sakas	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: carcinoma, renal cell	
Funding: FY 86: \$300.	FY 87: \$300.
Gifts: Menogaril	Periodic Review Date: Mar 87 Decision: Completed

OBJECTIVE: To determine the response rate of metastatic renal cell carcinoma to a new drug, menogaril.

TECHNICAL APPROACH: Patients agreeing to the study will receive menogaril IV once every 28 days.

PROGRESS: No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

This study has just closed to patient accrual as it reached its targeted patient registrations.

# Detail Summary Sheet

Prot No: SWOG 8505(86)	Status: Ongoing
TITLE: Evaluation of Echinomycin in Advanced Soft Tissue Sarcomas, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC; MAJ Luke M. Stapleton, MC; Ms. Mary MacMillan, RPH; LTC Lawrence Sakas, MC	
Department/Section: Medicine/Adult Hematology-Oncology	
Key Words: sarcoma, soft tissue	
Funding: FY 86: \$300.	FY 87: \$300.
Gifts: Echinomycin	Periodic Review Date: Sep 87 Decision: Continue

OBJECTIVE: To assess anti-tumor activity in patients with advanced sarcomas when treated with Echinomycin.

TECHNICAL APPROACH: Patients agreeing to participate will receive Echinomycin once a week IV for four weeks, then rest two weeks, then repeat the sequence.

PROGRESS: No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This protocol was approved in September 1986. This study remains open presently.

### Detail Summary Sheet

Prot No: SWOG 8507(86)	Status: Ongoing
TITLE: Maintenance vs No Maintenance BCG Immunotherapy of Superficial Bladder Cancer, Phase III	
Principal Investigator: COL Douglas Soderdahl, MC	
Associate Investigators: LTC W. Kennon, MC; MAJ F. Sateri, MC; CPT Karl Kreder, MC; CPT M. Pliskin, MC; LTC Lawrence Sakas, MC	
Department/Section: Surgery/Urology Svc	
Key Words: bladder cancer	
Funding: FY 86: \$300.	FY 87: \$300.
Gifts: BCG NSC B116341	Periodic Review Date: Apr 87 Decision: Continue

**OBJECTIVE:** To compare effectiveness of maintenance vs no maintenance BCG and to assess relative toxicities of these two approaches and to assess the association of intermediate strength PPD skin test reactivity with disease-free status in patients so treated.

**TECHNICAL APPROACH:** Patients who meet criteria and who consent to participate will be registered for induction treatment, then randomized at a second registration. BCG Connaughtis is diluted in 50.5 cc sterile saline and 50 cc is placed intravesically for two hours, 0.5 cc is administered subcutaneously to the upper thigh. Maintenance patients receive similar therapy weekly every six weeks.

**PROGRESS:** No. of Subjects Enrolled - To Date: 7      Reporting Period: 2

No data are available at this time. This study remains open.

Detail Summary Sheet

Prot No: SWOG 8509(86)	Status: Ongoing
TITLE: Evaluation of Menogaril in Adenocarcinoma of the Prostate, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse; MAJ Daniel T. Tell; LTC Lawrence Sakas	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: prostate adenocarcinoma	
Funding: FY 86: \$300.	FY 87: \$300.
Gifts: Menogaril	Periodic Review Date: Mar 87 Decision: Continue

OBJECTIVE: To determine the response rate of metastatic prostate cancer to a new Adriamycin-like drug, Menogaril, in patients who have failed hormone therapy.

TECHNICAL APPROACH: Patients agreeing to the study will receive the drug once every 28 days IV over one hour.

PROGRESS: No. of Subjects Enrolled - To Date: 1      Reporting Period: 0

No data are available at this time. This study remains open.

# Detail Summary Sheet

Prot No: SWOG 8513(86)	Status: Completed
TITLE: Evaluation of Menogaril (NSC-269148) in Pancreatic Adenocarcinoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC, MAJ Luke Stapleton, MC; Ms. Mary MacMillan, RPH; LTC Lawrence Sakas, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: carcinoma, pancreatic	
Funding: FY 86: \$300.	FY 87: \$300.
Gifts: Menogaril	Periodic Review Date: Sep 87 Decision: Completed

OBJECTIVE: To determine the response rate and response duration of advanced pancreatic carcinoma to a new drug, menogaril.

TECHNICAL APPROACH: Patients agreeing to the study will receive menogaril once a month as an IV infusion given over one hour.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This protocol was approved in September 1986.

This protocol is now permanently closed to patient accrual as it has just reached its targeted number of patient registrations. No data are available yet.

Detail Summary Sheet

Prot No: SWOG 8514(86)	Status: Ongoing
TITLE: Randomized Comparison of Cisplatin + 5-Fluorouracil vs. CBDCA + 5-Fluorouracil vs. Methotrexate in Advanced Squamous Cell Carcinoma of the Head and Neck, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse; MAJ Daniel T. Tell; LTC Lawrence Sakas	
Department/Section: Medicine/Hematology-Oncology Service	
Key Words: carcinoma, squamous cell	
Funding: FY 86: \$300.	FY 87: \$300.
Gifts: CBDCA	Periodic Review Date: Mar 87 Decision: Continue

OBJECTIVE: To compare the response rate of two relatively new chemotherapy combinations (5-FU + Cisplatin vs. CBDCA + 5-FU) with standard therapy, i.e., methotrexate, in advanced head and neck cancer.

TECHNICAL APPROACH: Patients agreeing to the study will be randomized to receive one of three regimens: (1) methotrexate IV weekly, (2) Cisplatin + 5-FU IV every 4 weeks, or (3) CBDCA + 5-FU IV every 4 weeks.

PROGRESS: No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

This study opened recently. No results are available at this time. The one Tripler patient received the CBDCA arm of the study and had complete disappearance of his tumor.

### Detail Summary Sheet

Prot No: SWOG 8516(86)	Status: Ongoing
TITLE: A Phase III Comparison of CHOP vs m-BACOD vs ProMACE-CytaBOM vs MACOP-B in Patients with Intermediate and High-Grade Non-Hodgkin's Lymphoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC; MAJ Daniel T. Tell, MC; LTC Lawrence Sakas, MC	
Department/Section: Medicine/Adult Hematology-Oncology	
Key Words: Lymphoma, non-Hodgkin's	
Funding: FY 86: \$300. FY 87: \$300	Periodic Review Date: Jun 87
Gifts: None	Decision: Continue

**OBJECTIVE:** To determine which of the four leading chemotherapy programs for aggressive lymphomas is best in terms of response, survival, and toxicity.

**TECHNICAL APPROACH:** Patients agreeing to participate in this study will be randomized to receive one of the four treatment programs listed above.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study recently opened. No data are available at the present time. This is an extremely important protocol in that it compares the 4 leading programs for treating high grade lymphomas.



Detail Summary Sheet

Prot No: SWOG 8530(86)	Status: Ongoing
TITLE: Efficacy of Prednisone in Refractory and Relapsing Multiple Myeloma and Measurement of Glucocorticoid Receptors, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC, MAJ Luke Stapleton, MC; Ms. Mary MacMillan, RPH; LTC Lawrence Sakas, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: myeloma; glucocorticoid receptors	
Funding: FY 86: \$300.	FY 87: \$300.
Gifts: none	Periodic Review Date: Sep 87 Decision: Continue

OBJECTIVE: To estimate the response rate and duration of response with high dose prednisone in patients with refractory myeloma.

TECHNICAL APPROACH: Patients agreeing to participate will receive 100 mg of prednisone every other day for two weeks, then 50 mg every other day for ten weeks.

PROGRESS: No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

This protocol was approved in September 1986. The one patient entered at Tripler has had an excellent response to this therapy.

# Detail Summary Sheet

Prot No: SWOG 8561(86) Status: Ongoing

TITLE: V-TAD for Patients Greater than 50 Years of Age with Acute Non-lymphocytic leukemia.

Principal Investigator: COL Jeffrey Berenberg, MC

Associate Investigators: MAJ William Uphouse, MC; MAJ Luke Stapleton, MC;  
Ms. Mary MacMillan, RPH; LTC Lawrence Sakas, MC

Department/Section: Medicine/Adult Hematology/Oncology

Key Words: leukemia, non-lymphocytic

Funding: FY 86: \$300. FY 87: \$300. Periodic Review Date: Sep 87  
Gifts: none Decision: Continue

**OBJECTIVE:** To determine the complete remission rate and toxicity of a new chemotherapy regimen in individuals greater than 50 years of age with acute non-lymphocytic leukemia.

**TECHNICAL APPROACH:** Patients agreeing to participate will receive "V-TAD" chemotherapy (5-day course). Patients achieving complete remission will receive three consolidation courses of "V-TAD" and then no further therapy.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0 Reporting Period: 0

This protocol was approved in September 1986. This study remains open.

# Detail Summary Sheet

Prot No: SWOG 8565(86)	Status: Ongoing
TITLE: Evaluation of Menogaril (NSC-269148) in Colorectal Carcinoma, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC; MAJ Luke Stapleton, MC; Ms. Mary MacMillan, RPH; LTC Lawrence Sakas, MC	
Department/Section: Medicine/Adult Hematology-Oncology	
Key Words: carcinoma, colorectal	
Funding: FY 86: \$300.	FY 87: \$300.
Gifts: Menogaril	Periodic Review Date: Sep 87 Decision: Continue

**OBJECTIVE:** To determine the response rate and response duration of advanced colorectal carcinoma to a new drug, menogaril.

**TECHNICAL APPROACH:** Patients agreeing to the study will all receive menogaril once a month as a one-hour IV infusion.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This protocol was approved in September 1986. This study remains open.

Detail Summary Sheet

Prot No: SWOG 8597(86)	Status: Ongoing
TITLE: Randomized Phase III Intergroup Study of Supradiaphragmatic Irradiation in Stage II-A Seminoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC; MAJ Luke Stapleton, MC Ms. Mary MacMillan, RPH; LTC Lawrence Sakas, MC; LTC Aida Ronquillo, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: seminoma	
Funding: FY 86: \$300.	FY 87: \$300.
Gifts: none	Periodic Review Date: Sep 87 Decision: Continue

OBJECTIVE: To determine whether supradiaphragmatic radiation really adds anything to infradiaphragmatic radiation for stage II-A seminoma (i.e., enlarged retroperitoneal nodes on CT scan).

TECHNICAL APPROACH: Patients agreeing to participate in this study will be randomized to receive or not receive supradiaphragmatic radiation as part of their radiation for stage II-A seminoma.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This protocol was approved in September 1986. This study remains open. No data are available at this time.

### Detail Summary Sheet

Prot No: SWOG 8598 (87)	Status: Ongoing
TITLE: A Prospective Trial for Localized Cancer of the Esophagus: Comparing Radiation as a Single Modality to the Combination of Radiation and Chemotherapy, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: esophagus, cancer, radiation, chemotherapy	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Mar 87
Gifts: none	Decision: Continue

OBJECTIVE: To determine the role of chemotherapy for a potentially curable subset of patients with squamous cell cancer of the esophagus. Specifically, to determine if the combination of chemotherapy and radiation will add to the overall survival and cure of patients treated with the combination when compared to patients treated by radiation alone.

TECHNICAL APPROACH: Patients agreeing to the study will be randomized to receive (1) radiation alone (6400 rads in 6½ weeks) or (2) radiation (5,000 rads in 5 weeks) beginning simultaneously with four cycles of chemotherapy (cisplatin plus 5-FU).

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study has just opened very recently.

# Detail Summary Sheet

Prot No: SWOG 8590(85) (previously 8591)	Status: Ongoing
TITLE: Phase III Study to Determine the Effect of Combining Chemotherapy with Surgery and Radiotherapy for Resectable Squamous Cell Carcinoma of the Head and Neck	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC; MAJ Daniel Tell, MC;	
Department/Section: Medicine/Adult Hematology-Oncology	
Key Words: carcinoma, squamous cell	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Apr 87
Gifts: None	Decision: Continue

OBJECTIVE: To determine if adding chemotherapy will improve results of surgery and radiation for advanced (Stage III and IV) but resectable head and neck cancer.

TECHNICAL APPROACH: All patients agreeing to participate in the study will be randomized to receive (1) surgery, then radiation therapy, or (2) surgery, then three cycles of chemotherapy (cisplatinum plus 5-FU), then radiation.

PROGRESS: No. of Subjects Enrolled - To Date: 3      Reporting Period: 1

There are three TAMC patients on this study. Response data has not been released. The number of this protocol has been changed from 8591 to 8590.

Detail Summary Sheet

Prot No: SWOG 8594(86)	Status: Ongoing
TITLE: A Phase III Trial of Cis-platinum Alone or in Combination with Doxorubicin, Vinblastine and Methotrexate in Advanced Bladder Cancer	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC; MAJ Daniel T. Tell, MC; LTC Lawrence Sakas, MC	
Department/Section: Medicine/Adult Hematology-Oncology	
Key Words: cancer, bladder	
Funding: FY 86: \$300.	FY 87: \$300. Periodic Review Date: Jul 87
Gifts: None	Decision: Continue

OBJECTIVE: To determine if cis-platinum in combination with doxorubicin, vinblastine, and methotrexate is more effective than cis-platinum alone in the treatment of patients with advanced bladder cancer in terms of objective response rate, response duration, and survival.

TECHNICAL APPROACH: Patients agreeing to the study will be randomized to receive either (1) cis-platinum IV every 28 days until disease progression or (2) cis-platinum, doxorubicin, vinblastine, and methotrexate IV every four weeks until disease progression.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study remains open. No data are available at this time.

Detail Summary Sheet

Prot No: SWOG 8600(87)	Status: Ongoing
TITLE: A Randomized Investigation of High Dose Versus Standard Dose Cytosine Arabinoside With Daunorubicin In Patients With Acute Non-Lymphocytic Leukemia	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: cytosine arabinoside and daunorubicin	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Feb 87
Gifts: None	Decision: Continue

**OBJECTIVE:** To compare, among patients with acute non-lymphocytic leukemia, the rate of complete remission produced by induction regimens of either standard dose cytosine arabinoside and daunorubicin or high dose cytosine arabinoside and daunorubicin. Also to compare these 2 programs when used in the consolidation phase.

**TECHNICAL APPROACH:** Patients are randomized to receive standard or high dose cytosine arabinoside initially. If remission is achieved then patients are randomized again to receive standard or high dose cytosine arabinoside for consolidation.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study was opened recently.



### Detail Summary Sheet

Prot No: SWOG 8604(87)	Status: Ongoing
TITLE: Evaluation of 6-Thioguanine (6-TG) in Refractory and Relapsing Myeloma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: 6-Thioguanine (6-TG); refractory or relapsing myeloma	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Apr 87
Gifts: None	Decision: Continue

**OBJECTIVE:** To determine the antitumor activity of 6-Thioguanine (6-TG) in patients with refractory or relapsing myeloma.

**TECHNICAL APPROACH:** Patients agreeing to participate with receive 6-TG as an IV infusion over several minutes every three weeks until relapse.

**PROGRESS:** No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study remains open. No data are available yet.

# Detail Summary Sheet

Prot No: SWOG 8605 (86)	Status: Ongoing
TITLE: Cyclophosphamide, Ara-C Infusion and Vincristine for Relapsed or Refractory Extensive Small Cell Lung Cancer, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC; MAJ L. M. Stapleton, MC; CPT Scott Martin, MS; LTC Lawrence Sakas, MC; LTC Aida Ronquillo, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: lung cancer; small cell	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Feb 87
Gifts: None	Decision: Continue

OBJECTIVE: To determine the efficacy of a new chemotherapy combination in relapsing or refractory small cell lung cancer.

TECHNICAL APPROACH: Patients agreeing to participate will receive cytoxan and Ara-C every 3 weeks for four cycles, then prophylactic cranial irradiation, then two more cycles of the chemotherapy. Vincristine will also be given with the other two drugs.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

The study remains open. No data available yet.

### Detail Summary Sheet

Prot No: SWOG 8606 (86)	Status: Completed
TITLE: Treatment of Small Cell Lung Cancer Using an Intensive, Multidrug Weekly Treatment Program of Short Duration, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC; MAJ L. M. Stapleton, MC; CPT Scott Martin, MS; LTC Lawrence Sakas, MC; LTC Aida Ronquillo, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: Lung cancer	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Feb 87
Gifts: None	Decision: Completed

OBJECTIVE: To determine the response rate, response duration and survival of patients with limited and extensive small cell lung cancer using a new intensive weekly treatment program.

TECHNICAL APPROACH: Patients agreeing to participate will receive the above mentioned drugs for 16 weeks total and then receive prophylactic brain irradiation.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study has just been permanently closed as it has reached its patient accrual goal. This occurred very rapidly. No results are available yet.

### Detail Summary Sheet

Prot No: SWOG 8611(87)	Status: Ongoing
TITLE: A Randomized Trial of Two Schedules of Trimetrexate versus 5-Fluorouracil in Colorectal Carcinoma, Phase II-III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: Trimetrexate vs. 5-Fluorouracil in Colorectal Carcinoma	
Funding: FY 86: NA	FY 87: \$300.
Gifts: None	Periodic Review Date: Feb 87
	Decision: Continue

OBJECTIVE: To determine and compare the response rates, response durations and toxicities of trimetrexate given on two different schedules to patients with advanced colorectal cancer. Also to compare patient survival on trimetrexate versus that on 5FU.

TECHNICAL APPROACH: Patient agreeing to participate in the study are randomized to receive trimetrexate by either of 2 IV schedules on to receive 5FU IV.

PROGRESS: No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

The one TAMC patient has been randomized to receive trimetrexate and has had stable disease with this on follow-up CT scan. The study remains open.

# Detail Summary Sheet

Prot No: SWOG 8616(87)	Status: Ongoing
TITLE: Intergroup Phase III Randomized Study of Doxorubicin and Dacarbazine With or Without Ifosfamide and Mesna in Advanced Soft Tissue and Bone Sarcoma	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC	
Department/Section: Medicine/Adult Hematology-Oncology	
Key Words: ifosfamide, mesna	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Aug 87
Gifts: None	Decision: Continue

OBJECTIVE: To determine if adding ifosfamide and mesna to the usually employed drugs of doxorubicin and dacarbazine will improve the response rate, response duration and survival in metastatic soft tissue and bone sarcoma.

TECHNICAL APPROACH: Patients agreeing to participate will have a central line (port-a-cath) placed and receive 4 days of doxorubicin and dacarbazine continuously through this line. These patients will also be randomized to receive or not receive 4 days of therapy with ifosfamide and mesna. These latter drugs are given together through a peripheral IV (in patients randomized to receive them). This whole chemotherapy regimen is repeated every 3 weeks until disease progression is noted.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study just opened for patient accrual.

Detail Summary Sheet

Prot No: SWOG 8617(87)	Status: Ongoing
TITLE: Evaluation of Interleukin 2 in Metastatic Renal Cell Carcinoma, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC	
Department/Section: Medicine/Adult Hematology-Oncology	
Key Words: Metastatic Renal Cell Carcinoma	
Funding: FY 86: NA	FY 87: \$300.
Gifts: None	Periodic Review Date: Aug 87
	Decision: Continue

**OBJECTIVE:** To determine the response rate and the remission duration in metastatic renal cell carcinoma treated with Interleukin 2.

**TECHNICAL APPROACH:** Patients agreeing to participate in this study will receive Interleukin 2 by IV bolus three times a week until disease progression is noted.

**PROGRESS:** No. of Subjects Enrolled - To Date: 1      Reporting Period: 1

One TAMC patient has been enrolled and has had almost complete resolution of her pulmonary metastases. The study remains open.

# Detail Summary Sheet

Prot No: SWOG 8624(87)	Status: Ongoing
TITLE: A Phase III Randomized Trial of Combination Therapy for Multiple Myeloma (1) Comparison of VMCP/VBAP to VAD or VMCP/VPBP for Induction; (2) Alpha-2b Interferon or No Therapy for Maintenance; and (3) Alpha-2b Interferon + Dexamethasone for Incomplete or Non-Responders	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC	
Department/Section: Medicine/Hematology-Oncology	
Key Words: multiple myeloma; Alpha-2b interferon	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Apr 87
Gifts: None	Decision: Continue

OBJECTIVE: (1) To compare SWOG's best induction chemotherapy program for myeloma with two other very promising programs; (2) to determine if interferon is a better maintenance program than no treatment; and (3) to determine if interferon plus decadron can salvage patients who do not respond satisfactorily to the above induction programs.

TECHNICAL APPROACH: Patients agreeing to the study will be randomized to receive one of the three induction programs. Those who achieve a response (75% M-protein reduction) will be randomized to receive or not receive interferon. Those not achieving response will be offered the above salvage program.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study has just opened.

### Detail Summary Sheet

Prot No: SWOG 8632(87)	Status: Ongoing
TITLE: Evaluation of Echinomycin in Central Nervous Systems Tumors, Phase II	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse, MC	
Department/Section: Medicine/Adult Hematology-Oncology	
Key Words: Echinomycin	
Funding: FY 86: \$300. FY 87: \$300.	Periodic Review Date: Aug 87
Gifts:	Decision: Continue

OBJECTIVE: To assess the efficacy of echinomycin in recurrent or residual central nervous system tumors by evaluation of response rate, response duration, and survival.

TECHNICAL APPROACH: Patients agreeing to participate in the study will receive courses of treatment (once a week IV for 4 weeks then 2 weeks rest) until disease progression is noted.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study has just opened.



Detail Summary Sheet

Prot No: SWOG 8642(87)	Status: Ongoing
TITLE: Recombinant Human Interferon-Gamma for the Adjuvant Treatment of High Risk Malignant Melanoma after Surgical Excision of the Primary Lesion, Phase III	
Principal Investigator: COL Jeffrey Berenberg, MC	
Associate Investigators: MAJ William J. Uphouse	
Department/Section: Medicine/Adult Hematology-Oncology	
Key Words: Recombinant Human Interferon-Gamma	
Funding: FY 86: NA	FY 87: \$300.
Gifts: None	Periodic Review Date: Aug 87
	Decision: Continue

OBJECTIVE: To compare the survival and disease-free survival among patients who are at high risk for recurrence of melanoma following resection of all know disease, and who are randomized to receive recombinant human interferon-gamma adjuvant therapy or no adjuvant therapy.

TECHNICAL APPROACH: Patients agreeing to participate in the study will be randomized to receive or not receive interferon-gamma subcutaneously once a day for 12 months.

PROGRESS: No. of Subjects Enrolled - To Date: 0      Reporting Period: 0

This study has just opened.

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